

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION,

)
)
)
)
)
)Case No.
)1:19-md-2875-RBK

THIS DOCUMENT RELATES TO ALL ACTIONS

)
)
)

DAY 1

CONFIDENTIAL

VIDEOTAPED DEPOSITION OF

DIPAK PANIGRAHY, M.D.

THURSDAY, SEPTEMBER 9, 2021

9:25 a.m. - 5:50 p.m.

GREENBERG TRAURIG LLP

ONE INTERNATIONAL PLACE, SUITE 2000

BOSTON, MASSACHUSETTS

Reported by: Sandra A. Deschaine, CSR, RPR,
CLR, CRA

<p style="text-align: right;">Page 2</p> <p>1 SEPTEMBER 9, 2021</p> <p>2</p> <p>3 9:25 a.m.</p> <p>4</p> <p>5 Videotaped Deposition of Dipak</p> <p>6 Panigrahy, M.D., held at Greenberg Taurig,</p> <p>7 LLP, One International Place, Boston,</p> <p>8 Massachusetts, pursuant to Notice, before</p> <p>9 Sandra A. Deschaine, a Shorthand Reporter,</p> <p>10 Registered Professional Reporter, Certified</p> <p>11 LiveNote Reporter, and Notary Public in and</p> <p>12 for the Commonwealth of Massachusetts.</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 4</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2 ON BEHALF OF THE PLAINTIFFS:</p> <p>3 MARTIN HARDING & MAZZOTTI LLP</p> <p>4 Rosemarie Bogdan, Esquire</p> <p>5 1 Wall Street</p> <p>6 Albany, New York 12205</p> <p>7 518.862.1200</p> <p>8 rosemarie.bogdan@1800law1010.com</p> <p>9</p> <p>10 ON BEHALF OF THE PLAINTIFFS:</p> <p>11 KANNER & WHITELEY, LLC</p> <p>12 Layne Hilton, Esquire (Via Zoom)</p> <p>13 701 Camp Street</p> <p>14 New Orleans, Louisiana 70130</p> <p>15 504.524.5777</p> <p>16</p> <p>17 ON BEHALF OF HJ HARKINS AND CIJEN:</p> <p>18 HINSHAW & CULBERTSON</p> <p>19 Kathleen Kelly, Esquire (Via Zoom)</p> <p>20 53 State Street, 27th Floor</p> <p>21 Boston, Massachusetts 02109</p> <p>22 617.231.7000</p> <p>23 kekelley@hinshawlaw.com</p> <p>24</p> <p>25 (Appearances continued.)</p>
<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S:</p> <p>2 ON BEHALF OF TEVA PHARMACEUTICALS:</p> <p>3 GREENBERG TRAURIG LLP</p> <p>4 Stephen Fowler, Esquire</p> <p>5 2101 L Street, N.W., Suite 1000</p> <p>6 Washington, D.C. 20037</p> <p>7 202.530.8587</p> <p>8 forlerst@gtlaw.com</p> <p>9 and</p> <p>10 Steven Harkins, Esquire</p> <p>11 Kenneth Dzikowski, Esquire (Via Zoom)</p> <p>12 333 Piedmont Road NE, Suite 2500</p> <p>13 Atlanta, Georgia 30350</p> <p>14 678.553.2312</p> <p>15 harkinss@gtlaw.com</p> <p>16</p> <p>17 ON BEHALF OF THE PLAINTIFFS AND THE WITNESS:</p> <p>18 LEVIN PAPANTONIO RAFFERTY</p> <p>19 Daniel Nigh, Esquire</p> <p>20 316 South Baylen Street</p> <p>21 Pensacola, Florida 32502</p> <p>22 850.435.7013</p> <p>23 dnigh@levinlaw.com</p> <p>24</p> <p>25 (Appearances continued.)</p>	<p style="text-align: right;">Page 5</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2 ON BEHALF OF AUROBINDO PHARMA LIMITED:</p> <p>3 CIPRIANI & WERNER, P.C.</p> <p>4 Jessica Heinz, Esquire (Via Zoom)</p> <p>5 450 Sentry Parkway, Suite 200</p> <p>6 Blue Bell, Pennsylvania 19422</p> <p>7 610.567.0700</p> <p>8 jheinz@c-wlaw.com</p> <p>9</p> <p>10 ON BEHALF OF HUMANA PHARMACY, INC.:</p> <p>11 FALKENBERG IVES LLP</p> <p>12 Megan Zmick, Esquire (Via Zoom)</p> <p>13 230 W. Monroe Street, Suite 2220</p> <p>14 Chicago Illinois 60606</p> <p>15 312.566.4808</p> <p>16 mas@falkenbergives.com</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 (Appearances continued.)</p>

<p style="text-align: right;">Page 6</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2 ON BEHALF OF MYLAN PHARMACEUTICALS:</p> <p>3 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI</p> <p>4 LLP:</p> <p>5 Clem Trischler, Esquire (Via Zoom)</p> <p>6 Frank Stoy, Esquire (Via Zoom)</p> <p>7 Jason Reefer, Esquire (Via Zoom)</p> <p>8 Bradley Matta, Esquire (Via Zoom)</p> <p>9 One Oxford Centre</p> <p>10 Pittsburgh, Pennsylvania 15219</p> <p>11 412.263.4246</p> <p>12 cct@pietragallo.com</p> <p>13 fhs@pietragallo.com</p> <p>14</p> <p>15 ON BEHALF OF THE DEFENDANTS ZHEJIANG HUAHAI</p> <p>16 PHARMACEUTICAL CO., LTD., PRINSTON</p> <p>17 PHARMACEUTICAL, INC., AND SOLCO HEALTHCARE</p> <p>18 LLC AND HUAHAI U.S., INC.:</p> <p>19 DUANE MORRIS LLP</p> <p>20 Frederick Ball, Esquire (Via Zoom)</p> <p>21 100 High Street, Suite 2400</p> <p>22 Boston, Massachusetts 02110-1724</p> <p>23 312.277.1945</p> <p>24 frball@duanemorris.com</p> <p>25 (Appearances continued.)</p>	<p style="text-align: right;">Page 8</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2</p> <p>3 ON BEHALF OF TEVE PHARMACEUTICALS:</p> <p>4 WALSH PIZZI O'REILLY FALANGA LLP</p> <p>5 Christine Gannon, Esquire (Via Zoom)</p> <p>6 Three Gateway Center</p> <p>7 100 Mulberry Street, 15th Floor</p> <p>8 Newark, New Jersey 07102</p> <p>9 973.757.1100</p> <p>10 cgannon@walsh.law</p> <p>11</p> <p>12</p> <p>13 ON BEHALF ALBERTSON'S LLC:</p> <p>14 BUCHANAN INGERSOLL & ROONEY PC</p> <p>15 Christopher Henry, Esquire (Via Zoom)</p> <p>16 227 West Trade Street, Suite 600</p> <p>17 Charlotte, North Carolina 28202</p> <p>18 704.444.3475</p> <p>19 christopher.henry@bipc.com</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 (Appearances continued.)</p>
<p style="text-align: right;">Page 7</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2</p> <p>3 ON BEHALF OF CVS AND RITE AID:</p> <p>4 BARNES & THORNBURG, LLP</p> <p>5 Kara Kapke, Esquire (Via Zoom)</p> <p>6 11 S. Meridian Street</p> <p>7 Indianapolis, Indiana 46204-3535</p> <p>8 317.231.6491</p> <p>9 kara.kapke@btlaw.com</p> <p>10</p> <p>11 ON BEHALF OF HUMANA PHARMACY, INC.:</p> <p>12 FALKENBERG IVES LLP</p> <p>13 Megan Zmick, Esquire (Via Zoom)</p> <p>14 230 W. Monroe Street, Suite 2220</p> <p>15 312.566.4808</p> <p>16 mas@falkenbergives.com</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 (Appearances continued.)</p>	<p style="text-align: right;">Page 9</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2</p> <p>3 ON BEHALF OF HETERO DRUGS AND HETERO LABS:</p> <p>4 HILL WALLACK LLP</p> <p>5 Nakul Shah, Esquire (Via Zoom)</p> <p>6 21 Roszel Road</p> <p>7 P.O. Box 5226</p> <p>8 Princeton, New Jersey 08543-5226</p> <p>9 nshah@hillwallack.com</p> <p>10</p> <p>11</p> <p>12 Also Present: Bob Giannini, videographer</p> <p>13 (Below via Zoom.)</p> <p>14 Ben Pelta Heller, concierge</p> <p>15 Coleen Hill, Duane Morris</p> <p>16 Dolores DeSalvo, Martin</p> <p>17 Hardinger & Mazzotti</p> <p>18 Ken Pzikowski</p> <p>19 Lauren Massey</p> <p>20 Liza Walsh</p> <p>21 Brett Vaughn</p> <p>22 Chicago37B</p> <p>23 16092139142</p> <p>24 14127134023</p> <p>25</p>

<p style="text-align: right;">Page 10</p> <p>1 INDEX</p> <p>2 EXAMINATION PAGE</p> <p>3 Dipak Panigrahy, M.D.</p> <p>4 By Mr. Fowler 15</p> <p>5</p> <p>6 EXHIBITS</p> <p>7 Exhibit Description Page</p> <p>8 Exhibit 1 Notice of Deposition 17</p> <p>9 Exhibit 2 Curriculum Vitae of 19</p> <p>10 Dipak Panigrahy, M.D.</p> <p>11 Exhibit 3 Flash drive 21</p> <p>12 Exhibit 4 Dr. Panigrahy's 23</p> <p>13 documents</p> <p>14 Exhibit 5 In Re: Actos 104</p> <p>15 (Pioglitazone) Products</p> <p>16 Liability Litigation</p> <p>17 (MDL 2299)</p> <p>18 Exhibit 6 Letter to Ned McWilliams 143</p> <p>19 from Dipak Panigrahy,</p> <p>20 M.D.</p> <p>21 Exhibit 7 Elsevier, attached 155</p> <p>22 Carcinogenesis: Failure</p> <p>23 of resolution of</p> <p>24 inflammation?</p> <p>25 Exhibit 8 Virtual exhibit 179</p> <p>26 Exhibit 9 Current criteria to 202</p> <p>27 establish human</p> <p>28 carcinogens</p> <p>29 (Exhibits continued.)</p>	<p style="text-align: right;">Page 12</p> <p>1 PROCEEDINGS</p> <p>2 THE VIDEOGRAPHER: Good morning.</p> <p>3 We are on the record. This is the</p> <p>4 videographer speaking, Bob Giannini,</p> <p>5 with Court Reporter Sandy Deschaine, 09:26 AM</p> <p>6 with Veritext Legal Solutions. Today's</p> <p>7 date is September 9th, 2021. The time</p> <p>8 is 9:25 a.m. We are currently located</p> <p>9 at the offices of Greenberg Traurig in</p> <p>10 Boston, Massachusetts, to take the video 09:26 AM</p> <p>11 deposition of Dr. Dipak Panigrahy in the</p> <p>12 matter of In Re: Valsartan Losartan, et</p> <p>13 al.</p> <p>14 Will counsel please introduce</p> <p>15 themselves for the record? 09:26 AM</p> <p>16 MR. NIGH: This is Daniel Nigh on</p> <p>17 behalf of the plaintiffs.</p> <p>18 MS. BOGDAN: Rosemarie Bogdan on</p> <p>19 behalf of the plaintiffs.</p> <p>20 MR. FOWLER: Stephen Fowler with 09:26 AM</p> <p>21 Greenberg Traurig on behalf of Teva</p> <p>22 Pharmaceuticals.</p> <p>23 MR. HARKINS: Steve Harkins with</p> <p>24 Greenberg Traurig on behalf of Teva</p> <p>25 Pharmaceuticals. 09:27 AM</p>
<p style="text-align: right;">Page 11</p> <p>1 INDEX (continued.)</p> <p>2 EXHIBITS (continued.)</p> <p>3 EXHIBIT DESCRIPTION PAGE</p> <p>4</p> <p>5 Exhibit 10 Intragastric formation 230</p> <p>6 and modulation of</p> <p>7 N-nitrosodimethylamine</p> <p>8 in a dynamic in vitro</p> <p>9 gastrointestinal model</p> <p>10 under human</p> <p>11 physiological conditions</p> <p>12 Exhibit 11 Endogenous versus 241</p> <p>13 exogenous exposure to</p> <p>14 N-nitroso compounds and</p> <p>15 gastric cancer risk in</p> <p>16 the European Prospective</p> <p>17 Investigation into</p> <p>18 Cancer and Nutrition</p> <p>19 (EPIC-EURGAST) study</p> <p>20 Exhibit 12 DNA adducts in humans 250</p> <p>21 after exposure to</p> <p>22 methylating agents</p> <p>23 Exhibit 13 Nitrosamines as 259</p> <p>24 Impurities in Drugs -</p> <p>25 Health Risk Assessment</p> <p>26 and Mitigation Public</p> <p>27 Workshop, March 29-30,</p> <p>28 2021</p> <p>29 Exhibit 14 Genetic and Cellular 307</p> <p>30 Basis of Multistep</p> <p>31 Carcinogenesis</p> <p>32 Exhibit 15 Concordance of 311</p> <p>33 thresholds for</p> <p>34 carcinogenicity of</p> <p>35 N-nitrosodiethylamine</p> <p>36 Exhibit 16 Thresholds in Chemical 323</p> <p>37 Carcinogenesis: What Are</p> <p>38 Animal Experiments</p> <p>39 Telling Us</p>	<p style="text-align: right;">Page 13</p> <p>1 THE VIDEOGRAPHER: Okay. Thank</p> <p>2 you. Will the court reporter please</p> <p>3 swear in the witness?</p> <p>4 THE REPORTER: I actually need to</p> <p>5 get people on the video, Bob. 09:27 AM</p> <p>6 (Off-the-video discussion.)</p> <p>7 MR. FOWLER: Folks on the phone,</p> <p>8 we're going to unmute you, and if you</p> <p>9 all could please introduce yourselves,</p> <p>10 the court reporter would like to get the 09:27 AM</p> <p>11 record started properly with the names</p> <p>12 of everybody who is attending. I</p> <p>13 understand we've done it differently,</p> <p>14 but let's do it this way today, please.</p> <p>15 MR. TRISCHLER: Clem Trischler, 09:28 AM</p> <p>16 T-r-i-s-c-h-l-e-r, representing Mylan</p> <p>17 Pharmaceuticals.</p> <p>18 MR. BALL: Frederick,</p> <p>19 F-r-e-d-e-r-i-c-k, last name, Ball, with</p> <p>20 Duane Morris, representing CHD, and with 09:28 AM</p> <p>21 me is my colleague Coleen, C-o-l-e-e-n,</p> <p>22 Hill, H-i-l-l.</p> <p>23 MS. KAPKE: Kara Kapke, K-a-p-k-e,</p> <p>24 for CVS and Rite Aid.</p> <p>25 MS. HILTON: Layne Hilton from 09:28 AM</p>

<p style="text-align: right;">Page 14</p> <p>1 Kanner and Whiteley on behalf of the</p> <p>2 plaintiffs.</p> <p>3 MS. KELLY: Kathleen Kelly of</p> <p>4 Hinshaw & Culbertson for HJ Harkins and</p> <p>5 Cijen. 09:28 AM</p> <p>6 MS. HEINZ: Jessica Heinz from</p> <p>7 Cipriani & Werner on behalf of the</p> <p>8 Aurobindo Defendants.</p> <p>9 MR. CASTLE: Andy Castle with</p> <p>10 Greenberg Traurig on behalf of Teva. 09:29 AM</p> <p>11 MS. ZMICK: Megan Zmick,</p> <p>12 Z-m-i-c-k, on behalf of Humana Pharmacy,</p> <p>13 Inc.</p> <p>14 MR. STOY: Frank Stoy, S-t-o-y,</p> <p>15 from Petro Gallo, also on behalf of the 09:29 AM</p> <p>16 Mylan Defendants.</p> <p>17 MR. REEFER: Jason Reefer,</p> <p>18 R-e-e-f-e-r, for Mylan.</p> <p>19 MR. HENRY: Christopher Henry on</p> <p>20 behalf of Albertson's, LLC. 09:29 AM</p> <p>21 MR. MATTA: Brad Matta, M-a-t-t-a,</p> <p>22 on behalf of Mylan Defendants.</p> <p>23 MS. DESALVO: Dolores DeSalvo,</p> <p>24 D-e-S-a-l-v-o, and I'm with Martin</p> <p>25 Harding and Mazzotti. I'm a nonattorney 09:30 AM</p>	<p style="text-align: right;">Page 16</p> <p>1 Center, Harvard Medical School.</p> <p>2 Q. And the street address, sir?</p> <p>3 A. 99 Brookline Avenue, Boston, Mass.</p> <p>4 Q. Doctor, I know you've given a</p> <p>5 couple depositions, so I'll cut some of the 09:32 AM</p> <p>6 ground rules short. But simply say that if</p> <p>7 you don't understand a question that I ask</p> <p>8 you, please let me know. There's a lot of</p> <p>9 medical jargon, and I may slip up. So if you</p> <p>10 don't understand my question, let me know. 09:32 AM</p> <p>11 And will it be fair for me to</p> <p>12 assume if you answer my question, that you've</p> <p>13 understood it?</p> <p>14 A. Correct.</p> <p>15 Q. Okay. And a lot of my questions 09:32 AM</p> <p>16 today may simply call for a yes-or-no answer,</p> <p>17 and I may or may not ask you to then</p> <p>18 elaborate on it. Sometimes, it may be a</p> <p>19 small question. So if you can answer that,</p> <p>20 and then if I ask you to explain, of course, 09:32 AM</p> <p>21 you're given that opportunity.</p> <p>22 Does that make sense to you?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And, of course, you know,</p> <p>25 this is less formal than court, so if you 09:32 AM</p>
<p style="text-align: right;">Page 15</p> <p>1 assisting Rosemarie.</p> <p>2 MR. FOWLER: Thank you everyone on</p> <p>3 the Zoom. I appreciate that.</p> <p>4 THE VIDEOGRAPHER: Still hasn't</p> <p>5 been sworn in. 09:31 AM</p> <p>6 DIPAK PANIGRAHY, M.D., Deponent,</p> <p>7 having first been satisfactorily identified</p> <p>8 by the production of his Massachusetts</p> <p>9 driver's license and duly sworn by the Notary</p> <p>10 Public, was examined and testified as 09:31 AM</p> <p>11 follows:</p> <p>12 EXAMINATION</p> <p>13 BY MR. FOWLER:</p> <p>14 Q. Good morning, again,</p> <p>15 Dr. Panigrahy. My name is Steve Fowler. We 09:31 AM</p> <p>16 were previously introduced this morning</p> <p>17 before the start of the deposition. And as</p> <p>18 you heard, I represent Teva Pharmaceuticals.</p> <p>19 Would you please state your full</p> <p>20 name and professional address. 09:31 AM</p> <p>21 A. Sure. First, Dipak Panigrahy.</p> <p>22 And -- what was your other</p> <p>23 question?</p> <p>24 Q. Your professional address, please.</p> <p>25 A. Beth Israel Deaconess Medical 09:31 AM</p>	<p style="text-align: right;">Page 17</p> <p>1 need a break at any time, please let me know.</p> <p>2 If there's not a question pending we can do</p> <p>3 that. We've got water over there. We'll try</p> <p>4 to take a break every hour or so just to keep</p> <p>5 everyone fresh. Okay? 09:33 AM</p> <p>6 A. Thank you.</p> <p>7 Q. Let's go ahead, please, and we're</p> <p>8 going to mark Exhibit 1, which is the Notice</p> <p>9 of Deposition.</p> <p>10 (Exhibit 1, Notice of Deposition, marked for 09:33 AM</p> <p>11 identification.)</p> <p>12 MR. FOWLER: And, Counsel, I'll</p> <p>13 apologize for flipping these to you all</p> <p>14 day. Okay?</p> <p>15 MR. NIGH: Best we can, yep. 09:33 AM</p> <p>16 MR. FOWLER: And, Rosemarie, if</p> <p>17 you'd like a copy too, I'll double-flip</p> <p>18 them, but -- see, this is not -- I'm</p> <p>19 not -- Steve will handle those going on.</p> <p>20 You should see me pitch 09:33 AM</p> <p>21 softball.</p> <p>22 MR. NIGH: You had a pretty good</p> <p>23 flip, though; you got them, so you did</p> <p>24 well.</p> <p>25 MR. FOWLER: Oh, wait, wait. What 09:34 AM</p>

<p style="text-align: right;">Page 18</p> <p>1 did I hand you? Did I hand you 2 objections or the notice? 3 THE REPORTER: Objections. 4 MR. FOWLER: Can I have the 5 notice? 09:34 AM 6 Bumpy start out of the gates. 7 Bear with me. 8 For the time being, let's -- we'll 9 have a placeholder. 10 BY MR. FOWLER: 09:34 AM 11 Q. Exhibit 1 is the notice of video 12 deposition requesting your appearance today, 13 and thank you for being here in person. 14 Doctor, do you recall seeing the 15 Notice of Deposition? 09:34 AM 16 A. Yes. 17 Q. And there was what we refer to as 18 an Exhibit A. It's a list of things that we 19 request that you provide to us. 20 Do you recall seeing that? 09:34 AM 21 A. Yeah. 22 Q. And one of those things we 23 requested was your current CV. And that's 24 something that you provided to your counsel? 25 A. Yes. 09:35 AM</p>	<p style="text-align: right;">Page 20</p> <p>1 And if this is July 2020, it's likely not 2 included. 3 A. Yes, the 2021 article is a review, 4 so it doesn't go under publications, but I 5 can add that. I can update the -- 09:37 AM 6 Q. Oh, that's fine, sir. I'm not 7 actually asking you to do any work. I just 8 want to make sure it's current and that, you 9 know, perhaps that's the only thing that's 10 not on there. 09:38 AM 11 Maybe, if you'd like, you know, to 12 take a look at your various sections, for 13 instance, presentations, and let me know if 14 there's anything like that that may be 15 missing from your CV or this version of your 09:38 AM 16 CV. 17 A. Yeah, this has -- so because of 18 COVID, we weren't -- we didn't have 19 presentations in 2020. So that's why this CV 20 has the updated in-person presentations. 09:38 AM 21 Q. Okay. Fair enough. Fair enough. 22 So this was provided to us, and, 23 Doctor, pursuant to the notice and the 24 protocol here in the litigation, your counsel 25 provided documents in response to the 09:39 AM</p>
<p style="text-align: right;">Page 19</p> <p>1 Q. Let me mark Exhibit 2, your CV, 2 sir. 3 (Exhibit 2, Curriculum Vitae of Dipak 4 Panigrahy, M.D., marked for identification.) 5 MR. FOWLER: Two copies coming 09:35 AM 6 over. 7 Can we hand the witness Exhibit 2? 8 THE WITNESS: Thank you. 9 BY MR. FOWLER: 10 Q. Doctor, Exhibit 2, I've marked as 09:36 AM 11 your CV and if you look in the top left, you 12 see date prepared as July 2020. Is this your 13 most current CV, sir? 14 A. Yeah, this is -- about every one 15 or two years I'll update my CV for -- with 09:36 AM 16 publications. This is -- this is very 17 similar to if I went through and added any -- 18 yeah, this is an updated CV. 19 Q. Well, I know for certain that it 20 doesn't have your 2021 article on it, so let 09:36 AM 21 me ask you again for a clear answer. 22 Do you think that is your current 23 CV, Doctor? If not, I'm going to request an 24 updated version. Simply, I only know that 25 because I've looked at your 2021 article. 09:37 AM</p>	<p style="text-align: right;">Page 21</p> <p>1 request, provided those on Tuesday, and what 2 I'd like to do is mark as Exhibit 3 a flash 3 drive containing the entire production from 4 the plaintiff on Tuesday. 5 MR. FOWLER: That will be 09:39 AM 6 Exhibit 3, please. 7 (Exhibit 3, Flash drive, marked for 8 identification.) 9 MR. NIGH: Yeah, we would just 10 object because there's no way for us to 09:39 AM 11 know if it's the entire, you know, 12 production, so -- with being a flash 13 drive here. 14 BY MR. FOWLER: 15 Q. So, Doctor, I notice, in addition 09:40 AM 16 to what's been provided on the flash drive or 17 maybe it's the same, you brought certain 18 documents with you today, correct? 19 A. Correct. 20 Q. And you have a pile right in front 09:40 AM 21 of you and a pile up at about 11 o'clock in 22 front of you, correct? 23 A. Correct. 24 Q. And you brought both of those with 25 you today? 09:40 AM</p>

<p style="text-align: right;">Page 22</p> <p>1 A. Correct.</p> <p>2 Q. One of the instructions will be</p> <p>3 definitely to answer verbally.</p> <p>4 A. Yes. Yes.</p> <p>5 Q. And what you've brought before you 09:40 AM</p> <p>6 are documents that you selected?</p> <p>7 A. Yes.</p> <p>8 Q. And you brought those with you</p> <p>9 today because those are documents that you're</p> <p>10 relying upon for your opinions in this case? 09:40 AM</p> <p>11 A. Well, my -- yeah, my report was</p> <p>12 over 250 pages. So I wanted to have the full</p> <p>13 report with me, and I have a couple</p> <p>14 publications that I also wanted to have with</p> <p>15 me too. 09:40 AM</p> <p>16 Q. Yes, sir. And the publications,</p> <p>17 out of the 500-plus that you cited in your</p> <p>18 report, you selected some subset of that to</p> <p>19 bring with you today, correct?</p> <p>20 A. Yes. 09:41 AM</p> <p>21 Q. And is everything that you brought</p> <p>22 with you today articles that are referenced</p> <p>23 in your report, or are there new articles?</p> <p>24 A. Yes, these are all referenced in</p> <p>25 my report. 09:41 AM</p>	<p style="text-align: right;">Page 24</p> <p>1 Briefly, though, what I'd like to</p> <p>2 do is take a quick look through, if I may.</p> <p>3 A. Yeah.</p> <p>4 Q. Thank you. I won't take anything</p> <p>5 out of order. I'm just kind of looking to 09:42 AM</p> <p>6 see if we've got some marks and things like</p> <p>7 that.</p> <p>8 Okay. That's your entire report.</p> <p>9 I've got one just like this.</p> <p>10 A. Okay. 09:42 AM</p> <p>11 Q. May I please see the articles.</p> <p>12 A. Sure.</p> <p>13 Q. Thank you.</p> <p>14 Okay. I'm just going to kind of</p> <p>15 rattle off what we've got. We've got Hidajat 09:42 AM</p> <p>16 with some highlighting. We've got Dr. Song's</p> <p>17 2015 dietary nitrates. We've got Dr. Pobel's</p> <p>18 1995 nitrosamine, nitrate, nitrite. I'm not</p> <p>19 going to list all of them. Let me just look</p> <p>20 through. I'll make a copy. 09:43 AM</p> <p>21 And fair to say, Doctor, places</p> <p>22 that you've highlighted on these documents</p> <p>23 were places in the article that you -- that</p> <p>24 were important to you?</p> <p>25 A. Yes. 09:43 AM</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. And are there any new articles</p> <p>2 that you have with you today that are not</p> <p>3 referenced in your report?</p> <p>4 A. No.</p> <p>5 Q. And the copies you have with you 09:41 AM</p> <p>6 today, are those copies that you have been</p> <p>7 working with, so to speak, as you prepared</p> <p>8 your report, or were they more recently</p> <p>9 printed?</p> <p>10 A. These were more -- as I was 09:41 AM</p> <p>11 preparing for the deposition, I printed them,</p> <p>12 just to make it easier to follow the studies.</p> <p>13 Q. Okay.</p> <p>14 What I would like to do is mark as</p> <p>15 Exhibit 4 everything that you've brought with 09:41 AM</p> <p>16 you, and we'll make a copy during the break.</p> <p>17 I don't want to deprive you of what you have,</p> <p>18 but is that -- would that be okay?</p> <p>19 A. Fine. Yeah.</p> <p>20 (Exhibit 4, Dr. Panigrahy's documents, 09:41 AM</p> <p>21 marked for identification.)</p> <p>22 BY MR. FOWLER:</p> <p>23 Q. And, of course, during the</p> <p>24 deposition, you can feel free to refer to</p> <p>25 your report or to any of those articles. 09:41 AM</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. And these articles, for example,</p> <p>2 are these articles that you yourself</p> <p>3 researched and retrieved, or are any of these</p> <p>4 articles provided by counsel?</p> <p>5 A. No, these are all articles I 09:43 AM</p> <p>6 myself researched and viewed relevant to</p> <p>7 my -- to the report.</p> <p>8 Q. Yes, sir. And in your -- in your</p> <p>9 office, I imagine, as a research scientist,</p> <p>10 you've got papers and journals everywhere. 09:44 AM</p> <p>11 Did you have a preexisting file</p> <p>12 on -- in nitrosamines or NDMA prior to your</p> <p>13 engagement in this litigation?</p> <p>14 A. No.</p> <p>15 Q. For this litigation, sir, do you 09:44 AM</p> <p>16 keep a file for this case?</p> <p>17 A. So for this case, it involved</p> <p>18 researching hundreds of publications. Some</p> <p>19 of them I'll just keep an electronic PDF in a</p> <p>20 folder, and other ones, I may print. Lately, 09:44 AM</p> <p>21 we left -- we don't print as often, so we</p> <p>22 rely on electronic PDFs. A lot of the</p> <p>23 downloading of papers these days are</p> <p>24 from obscure journals, so we either download</p> <p>25 the paper -- 09:44 AM</p>

<p style="text-align: right;">Page 26</p> <p>1 THE REPORTER: Are from what</p> <p>2 journals?</p> <p>3 THE WITNESS: Not-so-common</p> <p>4 journals.</p> <p>5 MR. FOWLER: Obscure, is what he 09:44 AM</p> <p>6 said.</p> <p>7 THE WITNESS: Obscure.</p> <p>8 So I'll either keep an electronic</p> <p>9 folder of the PDFs of the papers. Once</p> <p>10 in a while, if it's -- I'm kind of 09:45 AM</p> <p>11 old-fashioned. I like to read the</p> <p>12 paper, print it, and highlight it,</p> <p>13 old-fashioned if it's an important</p> <p>14 paper, so I do both.</p> <p>15 BY MR. FOWLER: 09:45 AM</p> <p>16 Q. And would I be correct that there</p> <p>17 are other hard copies of articles that you</p> <p>18 may have printed and highlighted that you</p> <p>19 elected not to bring today?</p> <p>20 A. Correct. Yes. 09:45 AM</p> <p>21 Q. You selected these out of your</p> <p>22 overall set?</p> <p>23 A. Yes.</p> <p>24 Q. And in that overall set, you also</p> <p>25 have notes and highlights on those articles? 09:45 AM</p>	<p style="text-align: right;">Page 28</p> <p>1 cited but even other publications. So a lot</p> <p>2 of what I do, I'll do electronically. I</p> <p>3 don't print the paper. So I use multiple</p> <p>4 papers that I haven't even cited.</p> <p>5 The research is very extensive on 09:46 AM</p> <p>6 NDMA and NDEA and cancer. And so for me to</p> <p>7 initiate the process of asking the question,</p> <p>8 does contaminated NDMA or NDEA in the</p> <p>9 valsartan pill cause human cancer, there's a</p> <p>10 whole scientific process that we -- that I 09:47 AM</p> <p>11 use that as a -- as a scientist in the field</p> <p>12 uses.</p> <p>13 So part of that process is to go</p> <p>14 through peer-reviewed papers and papers from</p> <p>15 government agencies like IARC, NPT, EPA, and 09:47 AM</p> <p>16 just find out which other papers, which may</p> <p>17 be relevant, read them, and then -- because</p> <p>18 there are thousands of papers we're talking.</p> <p>19 I only cited 500-something papers. But this</p> <p>20 field of nitrosamines and cancer and NDMA and 09:47 AM</p> <p>21 NDEA, I had to go through four lines of</p> <p>22 evidence.</p> <p>23 There's different types of studies</p> <p>24 I use. One is animals and cancer. Does NDMA</p> <p>25 or NDEA cause cancer in animals? These are 09:48 AM</p>
<p style="text-align: right;">Page 27</p> <p>1 A. Depends on the paper. Sometimes,</p> <p>2 if I'm highlighting an important fact or</p> <p>3 conclusion, I tend -- then I'll highlight it.</p> <p>4 Q. Okay. And you, obviously, have</p> <p>5 access to those articles; you're able to put 09:45 AM</p> <p>6 your hands on them when you leave here today?</p> <p>7 You've had those in your office?</p> <p>8 A. Yes.</p> <p>9 Q. I would ask for a copy, please, of</p> <p>10 any of the articles you didn't bring with you 09:45 AM</p> <p>11 today that may contain your -- any highlights</p> <p>12 or notes that you've made.</p> <p>13 Could you do that?</p> <p>14 A. Sure.</p> <p>15 Q. Through counsel, of course, sir. 09:46 AM</p> <p>16 A. Yeah.</p> <p>17 Q. Did you make any sorts of notes,</p> <p>18 handwritten notes or electronic notes? As</p> <p>19 you're reading some of these 500-plus</p> <p>20 articles, did you kind of capture the essence 09:46 AM</p> <p>21 in any sort of independent document?</p> <p>22 A. So part of the research, when I</p> <p>23 was asked the question here, does NDMA in</p> <p>24 valsartan cause human cancer, I have to</p> <p>25 research not only the 500 or so papers that I 09:46 AM</p>	<p style="text-align: right;">Page 29</p> <p>1 chemical carcinogenesis assays.</p> <p>2 Then I had to research mechanisms</p> <p>3 of animal tissues and cells. Can NDMA or</p> <p>4 NDEA affect mechanisms in these cells that</p> <p>5 are relevant to a chemical-causing cancer? 09:48 AM</p> <p>6 And then a third set of papers</p> <p>7 that I had to look up is human tissue and</p> <p>8 cells. Does NDMA or NDEA affect human</p> <p>9 tissues and cells?</p> <p>10 And the fourth is the human 09:48 AM</p> <p>11 epidemiology studies.</p> <p>12 So as I started to research the</p> <p>13 question of does NDMA or NDEA cause human</p> <p>14 cancer, by researching that topic with</p> <p>15 peer -- and I focused on peer-reviewed 09:48 AM</p> <p>16 papers. I do look at reviews too, but as far</p> <p>17 as -- as a scientist, we rely on</p> <p>18 peer-reviewed papers especially, because they</p> <p>19 go through a process where a paper is</p> <p>20 submitted to a journal, undergoes external 09:49 AM</p> <p>21 review by three -- usually a few independent</p> <p>22 scientists; and then, in order to be</p> <p>23 published, it has to undergo the correct</p> <p>24 controls according to those reviewers. So</p> <p>25 that's called a peer-reviewed publication. 09:49 AM</p>

<p style="text-align: right;">Page 30</p> <p>1 So I rely on that.</p> <p>2 And so even though I only cited</p> <p>3 583 publications, in that range, my research</p> <p>4 involves many more publications too that I</p> <p>5 used. 09:49 AM</p> <p>6 Q. Okay. Do you recall what my</p> <p>7 question was, sir? No.</p> <p>8 My question was did you make any</p> <p>9 notes --</p> <p>10 My question -- let me try again. 09:49 AM</p> <p>11 Did you make notes? Out of all</p> <p>12 this -- and thank you for your answer. Out</p> <p>13 of all of this different research you did,</p> <p>14 did you keep any notes?</p> <p>15 A. From the time I started in 2019 to 09:50 AM</p> <p>16 now on notes -- I don't understand the</p> <p>17 question.</p> <p>18 Q. Yeah, that's fine, Doctor.</p> <p>19 Did you make any notes? You just</p> <p>20 testified you've reviewed more than 500 09:50 AM</p> <p>21 articles. You gave a whole litany of your</p> <p>22 methodology, which I appreciate.</p> <p>23 My simple question is, do you have</p> <p>24 any notes from all that research?</p> <p>25 A. So what I -- I would have drafts 09:50 AM</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. So we've got those. And you said</p> <p>2 you have Word documents where you capture</p> <p>3 your thoughts when you've reviewed a paper.</p> <p>4 Did I understand that right?</p> <p>5 A. Yes. 09:51 AM</p> <p>6 Q. Okay. I'm requesting copies of</p> <p>7 both those things. I would like copies of</p> <p>8 the Word documents that you've testified</p> <p>9 have -- that you have and that you've created</p> <p>10 that summarize your thoughts as you went 09:51 AM</p> <p>11 through this process, and I would like a copy</p> <p>12 of any handwritten notes.</p> <p>13 We have Exhibit 1 now, the Notice</p> <p>14 of Deposition, sir, and I apologize for</p> <p>15 tossing it at you, but we absolutely 09:52 AM</p> <p>16 requested -- on page 7, if you -- if you look</p> <p>17 to that, you know, all notes, whether</p> <p>18 handwritten or in electronic format.</p> <p>19 Do you see that at the top? It's</p> <p>20 under 6B. It's on page 7. 09:52 AM</p> <p>21 So I'm just making the record,</p> <p>22 sir, that we asked for this. You've</p> <p>23 testified having seen the notice.</p> <p>24 So can you and will you produce to</p> <p>25 counsel copies of your electronic thoughts 09:52 AM</p>
<p style="text-align: right;">Page 31</p> <p>1 of my thoughts of these papers as I start to</p> <p>2 research. Usually, I do that rather than a</p> <p>3 printed copy, just a Word document.</p> <p>4 Q. I understand. I'm still waiting</p> <p>5 for an answer. Do you have notes, sir? You 09:50 AM</p> <p>6 said you -- you write thoughts on your</p> <p>7 papers?</p> <p>8 A. So I have Word documents of drafts</p> <p>9 of ideas when I'm starting to research</p> <p>10 different papers. 09:51 AM</p> <p>11 Q. Okay.</p> <p>12 A. I wouldn't say I had like a</p> <p>13 printed papers of the notes. Usually, I do</p> <p>14 everything on a Word document.</p> <p>15 Q. Okay. So let me -- let me just 09:51 AM</p> <p>16 try to be clear.</p> <p>17 You don't have any notepad of</p> <p>18 handwritten notes or anything like that. Is</p> <p>19 that what I'm hearing you say, or you do?</p> <p>20 A. Well, over -- the scientific 09:51 AM</p> <p>21 process, I do both. I do write notes --</p> <p>22 Q. Okay.</p> <p>23 A. -- as I'm researching a paper.</p> <p>24 Q. Yes, sir.</p> <p>25 A. So... 09:51 AM</p>	<p style="text-align: right;">Page 33</p> <p>1 and your handwritten notes, sir? That's</p> <p>2 really all I'm asking.</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And do you have any record</p> <p>5 of the articles in excess of the 580-some 09:52 AM</p> <p>6 articles that you cited that you reviewed,</p> <p>7 you considered, and you excluded from a</p> <p>8 reference in your report?</p> <p>9 Do you understand my question?</p> <p>10 A. Yes. A lot of those papers, I'll 09:53 AM</p> <p>11 read, and I won't save them. They may be --</p> <p>12 I'll read them and then -- because there's so</p> <p>13 many publications, you know, it could be over</p> <p>14 a thousand publications, you know, over the</p> <p>15 past 60 years. 09:53 AM</p> <p>16 But, yes, I do -- can -- I do have</p> <p>17 papers that I didn't reference that I could</p> <p>18 provide.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. If you've previously -- if you 09:53 AM</p> <p>21 have them saved. I'm not asking you --</p> <p>22 A. Yeah.</p> <p>23 Q. -- to reinvent your research --</p> <p>24 A. Right.</p> <p>25 Q. -- but if you -- in your 09:53 AM</p>

<p style="text-align: right;">Page 34</p> <p>1 electronic file that you've testified to, if 2 you have articles that you didn't cite here, 3 I would ask those also be included in what -- 4 I'll follow up with a letter to counsel 5 that -- with this request, but any of those 09:53 AM 6 articles, please include as well. 7 Okay? 8 A. Okay. 9 Q. Got it? 10 Do you keep copies of your prior 09:54 AM 11 deposition transcripts in your office, sir? 12 A. I do have a copy of the -- when I 13 did the Actos deposition, yes. 14 Q. Okay. Did counsel for plaintiffs 15 provide you with any materials? And I'm 09:54 AM 16 going to leave that as broadly as it sounds. 17 Did they send you any materials? 18 MR. NIGH: Form objection. 19 A. For -- 20 BY MR. FOWLER: 09:54 AM 21 Q. Fair enough. Let me -- let me 22 break it down. 23 Did counsel for plaintiffs provide 24 with you any articles to review in connection 25 with this case? 09:54 AM</p>	<p style="text-align: right;">Page 36</p> <p>1 A. No. 2 Q. Have you ever reviewed the 3 complaint that is filed on behalf of the 4 plaintiffs in this case? 5 A. I'm not sure I understand the 09:55 AM 6 question. 7 Q. The -- this litigation began with 8 the filing of a lawsuit by plaintiffs, 9 actually, more than one. 10 Have you ever received a copy of 09:56 AM 11 those pleadings? 12 A. No, I -- I think I focused on the 13 questions that they asked me. 14 Q. And we'll get to those, sir. 15 A. Yeah. 09:56 AM 16 Q. Am I understanding your answer, 17 that you've never seen a copy of the 18 complaint that's filed in this case? 19 A. I mean, I reviewed over a thousand 20 documents for this case. I don't -- I can't 09:56 AM 21 recall. I don't think so. 22 Q. Are you familiar with the 23 allegations in this case? 24 A. Yes. 25 Q. And how are you familiar with 09:56 AM</p>
<p style="text-align: right;">Page 35</p> <p>1 A. No. I do my own independent 2 peer-review process to answer the question. 3 So I do my own research. 4 Q. Did they send you any company 5 documents to look at? Do you understand what 09:54 AM 6 I mean by "company documents"? 7 MR. NIGH: Form objection. 8 A. Yes. There are levels of the NDMA 9 and NDEA in some of the valsartan tablets, so 10 that wasn't published. I rely on -- 09:55 AM 11 BY MR. FOWLER: 12 Q. I understand. My question -- 13 again, this was -- 14 A. Yeah. 15 Q. I appreciate the detail. 09:55 AM 16 Counsel sent you records from the 17 various defendants' companies that contain 18 information on the levels of their testing in 19 the valsartan tablets. 20 Is that what I'm understanding? 09:55 AM 21 A. Correct. 22 Q. Okay. Other than testing-related 23 documents, were you provided with any other 24 individual defendant company documents in 25 this case? 09:55 AM</p>	<p style="text-align: right;">Page 37</p> <p>1 that? 2 A. Yes. I was asked by the 3 plaintiffs, does NDMA or NDEA in the 4 valsartan cause human cancer. I was asked, 5 if that was the case, are there any tumor 09:56 AM 6 types. I was also asked about tumor latency, 7 that if it caused cancer, what would be a 8 reasonable latency period. 9 But my initial question focused in 10 on does NDMA and NDEA cause cancer in humans. 09:57 AM 11 Q. Okay. And thank you again for 12 that. 13 Are you familiar with the 14 allegations -- do you know what the term 15 "allegation" means in a lawsuit context, sir? 09:57 AM 16 A. Correct -- yes. 17 Q. Okay. What's your understanding 18 of what an allegation is? 19 A. That there's been an injury or 20 something wrong has been done by somebody, 09:57 AM 21 so... 22 Q. Okay. And, in this case, do you 23 know what the allegations are? 24 A. Yes, that people who took 25 valsartan for their high blood pressure or 09:57 AM</p>

<p style="text-align: right;">Page 38</p> <p>1 for the heart had probable human carcinogen, 2 NDMA or NDEA, in the valsartan. 3 Q. Okay. And? 4 A. And that caused their cancer. 5 Q. Okay. Thank you. 09:58 AM 6 And do you have an opinion -- 7 well, strike that. 8 Are you -- are you aware of what 9 the time period is at issue in this case 10 concerning the affected valsartan products? 09:58 AM 11 A. I'm not sure if I understand the 12 question. 13 Q. Do you know over what period of 14 time and over what years any of the 15 plaintiffs in this case may have taken 09:58 AM 16 affected valsartan tablets? 17 A. Yeah. So in July -- 18 MR. NIGH: Form objection. You 19 can answer. 20 A. July 5th, 2018, is when -- around 09:58 AM 21 that time is when the EMA had recalled -- had 22 looked at this question of does valsartan 23 have this NDMA/NDEA, and then they reviewed 24 it, and then there was a recall about 20 -- 25 2,000 batches of valsartan. 22 countries 09:59 AM</p>	<p style="text-align: right;">Page 40</p> <p>1 finish, sir. I'm not going to interrupt 2 you -- 3 A. Yeah. 4 Q. -- all day, but I am going to 5 reclaim my time for a lot of pages of 10:00 AM 6 nonresponsive answers. But that's for 7 another -- that's another matter. I want you 8 to do your best to answer my questions. 9 So my question again, sir, what 10 time period -- over what time period do you 10:00 AM 11 believe plaintiffs in this litigation may 12 have taken affected valsartan tablets? 13 MR. NIGH: Form objection. 14 A. I'd have to look at the -- around 15 the last four or five years, but I can't 10:00 AM 16 really recall exactly. I'd have to look at 17 the -- you know, I reviewed like a thousand 18 documents for this, so. 19 BY MR. FOWLER: 20 Q. Doctor, have you been provided 10:01 AM 21 with any copies of depositions that have 22 taken place in this litigation? 23 A. No. 24 Q. And by "no," you mean you have not 25 received any company witness transcripts, 10:01 AM</p>
<p style="text-align: right;">Page 39</p> <p>1 recalled the valsartan: Hong Kong, Pakistan, 2 regulatory agencies, and then the FDA 3 reviewed it. 4 So it was around this 2018 summer 5 when NDMA was first found in the valsartan, 09:59 AM 6 and then in September was the NDEA. So it 7 was around that time period is when this -- 8 these issues came up. 9 BY MR. FOWLER: 10 Q. Yes, sir. That's when it was 09:59 AM 11 found. 12 Do you or do you not have any 13 understanding of what years plaintiffs may 14 have been exposed or may have taken affected 15 valsartan? 09:59 AM 16 Do you understand that question? 17 A. Yes. 18 Q. Okay. What years do you believe 19 the plaintiffs in this case could have taken 20 affected valsartan tablets? 10:00 AM 21 MR. NIGH: Form objection. 22 A. So I would have to look at the 23 specific -- specific pills and the time -- so 24 I -- 25 Q. What -- go ahead. I'll let you 10:00 AM</p>	<p style="text-align: right;">Page 41</p> <p>1 correct? 2 A. Correct. 3 Q. Have you received any of the other 4 expert witness transcripts that have been 5 taken so far in this case of plaintiffs' 10:01 AM 6 experts, Dr. Madigan, Hecht, and Etminan? 7 A. No. 8 Q. You've not seen those? 9 A. No. No. 10 Q. Have you been given any 10:01 AM 11 understanding of what transpired in those 12 depositions? 13 A. No. 14 Q. Have you received the reports from 15 the other experts engaged by plaintiffs, 10:02 AM 16 Dr. Hecht, Etminan, Madigan? I'm sure I'm 17 missing something. 18 A. No, I relied on my own independent 19 peer review and my own scientific process. 20 Q. Yeah, I understand your reliance. 10:02 AM 21 I'm looking at what you've received. 22 Have you received any of the other 23 reports? Yes or no, Doctor? 24 A. No. 25 Q. Okay. Have you received all of 10:02 AM</p>

<p style="text-align: right;">Page 42</p> <p>1 the reports from defendants' experts?</p> <p>2 A. I received Dr. Chodosh's report.</p> <p>3 Q. Okay. What about Dr. Johnson's</p> <p>4 report?</p> <p>5 A. I don't -- I can't -- I don't -- 10:02 AM</p> <p>6 no, I didn't receive that one.</p> <p>7 Q. You didn't receive the report from</p> <p>8 Dr. George Johnson, the genetic toxicologist</p> <p>9 who's done extensive work on this subject?</p> <p>10 You didn't get his report? 10:02 AM</p> <p>11 A. No. I read his --</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. I read his publication.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. When did you read his publication? 10:03 AM</p> <p>16 A. It just came out in 2021, so I had</p> <p>17 read it as part of my review process.</p> <p>18 Q. And you elected not to include it</p> <p>19 in your report anywhere; isn't that correct?</p> <p>20 MR. NIGH: Form objection. 10:03 AM</p> <p>21 A. I have to -- let me see -- I</p> <p>22 recall -- I thought I -- cited --</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. I can represent 100 percent that</p> <p>25 Dr. Johnson's 2021 PDE article is not in your 10:03 AM</p>	<p style="text-align: right;">Page 44</p> <p>1 cancer -- they have -- they don't use -- for</p> <p>2 mutagenic chemicals that have no threshold,</p> <p>3 such as NDMA and NDEA, they don't use that.</p> <p>4 For nongenotoxic carcinogens that</p> <p>5 have a threshold, that's a different story. 10:05 AM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. So a BMD approach would be</p> <p>8 appropriate for genotoxic compounds that have</p> <p>9 a threshold?</p> <p>10 A. Genotoxic compound -- 10:05 AM</p> <p>11 MR. NIGH: Form objection.</p> <p>12 You can answer.</p> <p>13 A. Genotoxic compounds, by</p> <p>14 definition, and the papers I've cited in my</p> <p>15 paper -- in science we don't rely on one 10:05 AM</p> <p>16 paper. We rely on a whole series of</p> <p>17 publications. And genotoxic chemicals, such</p> <p>18 as NDMA and NDEA, do not have a threshold.</p> <p>19 They can cause cancer at any dose. There's a</p> <p>20 linear extrapolation based on Peto, based on 10:05 AM</p> <p>21 Terracini 1967, so --</p> <p>22 BY MR. FOWLER:</p> <p>23 Q. Doctor, respectfully, this is</p> <p>24 going to be an incredibly long day.</p> <p>25 If you -- if you can please -- I 10:06 AM</p>
<p style="text-align: right;">Page 43</p> <p>1 reference list.</p> <p>2 MR. NIGH: Form objection.</p> <p>3 A. I focused on the papers that I</p> <p>4 thought were relevant to NDMA and NDEA causes</p> <p>5 of cancer. And we can get into the TD 50s, 10:03 AM</p> <p>6 and the regulatory agencies use a TD 50.</p> <p>7 This is a genotoxic carcinogen and mutagenic.</p> <p>8 So I focused on the scientific processes that</p> <p>9 the leading regulatory agencies used like</p> <p>10 IARC, NTP, EPA, the European Medical 10:04 AM</p> <p>11 Association, Canada Health. So these five or</p> <p>12 six leading scientific agencies use a process</p> <p>13 and that was -- of determining whether a</p> <p>14 chemical can cause cancer in humans.</p> <p>15 BY MR. FOWLER: 10:04 AM</p> <p>16 Q. Yes, sir. Now, all of those</p> <p>17 agencies recognize and have approved the use</p> <p>18 of a benchmark dose testing where there is</p> <p>19 sufficient information on the</p> <p>20 carcinogenicity; isn't that correct? 10:04 AM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A. They have not -- yes -- well,</p> <p>23 they -- for a mutagenic chemical, such as</p> <p>24 NDMA and NDEA, which is a genotoxin, which</p> <p>25 can cause cancer -- even a molecule can cause 10:04 AM</p>	<p style="text-align: right;">Page 45</p> <p>1 understand all those things, and we're going</p> <p>2 to talk about them. This is just the</p> <p>3 beginning. I'm trying to get some</p> <p>4 understanding of your understanding.</p> <p>5 Let me ask again. 10:06 AM</p> <p>6 The benchmark dose method is a</p> <p>7 method of risk assessment for carcinogens</p> <p>8 that is recognized as appropriate in certain</p> <p>9 circumstances by FDA and EMA in the ICH</p> <p>10 M7(R1), correct? 10:06 AM</p> <p>11 A. Correct --</p> <p>12 MR. NIGH: Hold on. Hold on. My</p> <p>13 objection to the colloquy. It was</p> <p>14 clearly a responsive answer. His answer</p> <p>15 was interrupted. 10:06 AM</p> <p>16 And on top of that, your question</p> <p>17 had a loaded question to it. So his</p> <p>18 question [sic] was clearly responsive.</p> <p>19 MR. FOWLER: Well, how about --</p> <p>20 how about an objection, Counsel? And 10:06 AM</p> <p>21 saying something is loaded is absolutely</p> <p>22 not an objection.</p> <p>23 MR. NIGH: Hold on. We have a</p> <p>24 deposition protocol. We've had rulings</p> <p>25 on this, where if you start to speak to 10:07 AM</p>

<p style="text-align: right;">Page 46</p> <p>1 the witness that their answers are</p> <p>2 nonresponsive, that's been deemed</p> <p>3 inappropriate.</p> <p>4 MR. FOWLER: And that's why I'm</p> <p>5 staying -- I'm staying away from that. 10:07 AM</p> <p>6 But I am reclaiming my time for page</p> <p>7 after page, and this will be dealt with</p> <p>8 separately.</p> <p>9 MR. NIGH: These answers have been</p> <p>10 clearly responsive. 10:07 AM</p> <p>11 MR. FOWLER: Doctor --</p> <p>12 MR. NIGH: And at this point, I</p> <p>13 think it's becoming inappropriate. The</p> <p>14 statements of you're not answering my</p> <p>15 question or I'm going to reclaim my 10:07 AM</p> <p>16 time, that's just another way of saying</p> <p>17 nonresponsive.</p> <p>18 BY MR. FOWLER:</p> <p>19 Q. Doctor, can we agree that the BMD</p> <p>20 approach, the benchmark dose approach, is a 10:07 AM</p> <p>21 method that is recognized and approved by FDA</p> <p>22 and the EMA in the ICH M7(R1)?</p> <p>23 MR. NIGH: Form objection.</p> <p>24 A. I think, like I was saying, it is</p> <p>25 approved for certain chemicals and certain 10:07 AM</p>	<p style="text-align: right;">Page 48</p> <p>1 A. That could happen, yes.</p> <p>2 Q. And were you not interested in the</p> <p>3 most recent science on the risk, if any, from</p> <p>4 low-level exposure to NDMA?</p> <p>5 MR. NIGH: Form objection. 10:09 AM</p> <p>6 A. So as I said before, I did read</p> <p>7 carefully the European Medical Association</p> <p>8 ruling from 2020, the Health Canada ruling on</p> <p>9 NDMA. I've read WHO 2002. I've read the FDA</p> <p>10 guidance on this, and they all say -- or they 10:09 AM</p> <p>11 all agree that exposure to NDMA or NDEA is</p> <p>12 bad, and it should be minimized, and it can</p> <p>13 cause cancer. And they used the TD 50 from</p> <p>14 Peto as their ruling.</p> <p>15 Now, I can't anticipate what will 10:10 AM</p> <p>16 happen 10 years from now, but on my</p> <p>17 reasoning, was to look at the leading</p> <p>18 agencies that -- and they do this -- the</p> <p>19 classification of a -- whether a chemical can</p> <p>20 cause cancer, one of the leading respected 10:10 AM</p> <p>21 agencies for the last 50 years, since 1971,</p> <p>22 is IARC. IARC has written 120 monographs on</p> <p>23 this.</p> <p>24 And so what the EMA also</p> <p>25 independently looks at and what Canada -- 10:10 AM</p>
<p style="text-align: right;">Page 47</p> <p>1 carcinogens, not for genotoxic carcinogens.</p> <p>2 I haven't seen an agency use that for a</p> <p>3 mutagenic chemical such as NDMA or NDEA.</p> <p>4 BY MR. FOWLER:</p> <p>5 Q. Fair enough. 10:08 AM</p> <p>6 And am I correct that it's your</p> <p>7 testimony that you were aware of and you</p> <p>8 reviewed Dr. Johnson's 2021 article on NDMA</p> <p>9 and his calculations using the BMD approach,</p> <p>10 and you deemed it not relevant to your 10:08 AM</p> <p>11 opinions? Is that what I understood?</p> <p>12 A. When I cited the 583 publications,</p> <p>13 I focused on, in my opinion, what was</p> <p>14 relevant to determining is NDMA and NDEA a</p> <p>15 human carcinogen. And part of that reasoning 10:08 AM</p> <p>16 and thinking is I focus on what IARC, the</p> <p>17 FDA, and the EMA does. And to what -- I</p> <p>18 haven't seen a regulatory agency use that</p> <p>19 type of modeling to determine doses that are</p> <p>20 safe -- considered safe for people. 10:09 AM</p> <p>21 Q. Do you agree that science</p> <p>22 sometimes is on the leading -- let me start</p> <p>23 again.</p> <p>24 Do you agree that science is</p> <p>25 sometimes ahead of regulatory agencies? 10:09 AM</p>	<p style="text-align: right;">Page 49</p> <p>1 Health Canada independently looks at, is</p> <p>2 that -- what is very important and the bottom</p> <p>3 line, is that this is either a probable human</p> <p>4 carcinogen, a human carcinogen, or in the</p> <p>5 case of NTP and the Human Health Services, 10:11 AM</p> <p>6 reasonably anticipated to be a human</p> <p>7 carcinogen.</p> <p>8 So five or six of the leading</p> <p>9 scientific agencies that I included in my</p> <p>10 report all say that NDMA or NDEA is 10:11 AM</p> <p>11 reasonably or probably considered or likely a</p> <p>12 human carcinogen. And I spent the 200 pages</p> <p>13 devoted to that process.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. Since your report was provided to 10:11 AM</p> <p>16 us in July, have you added any articles or</p> <p>17 documents to your file for this litigation,</p> <p>18 sir?</p> <p>19 A. Part of my -- as being a</p> <p>20 scientist, every week I'll look on PubMed for 10:12 AM</p> <p>21 new papers, for new findings to see how the</p> <p>22 field advances. But I relied on the papers</p> <p>23 that I had prepared for this report.</p> <p>24 Q. My question, Doctor, was, since</p> <p>25 your report was provided to us, have you 10:12 AM</p>

<p style="text-align: right;">Page 50</p> <p>1 added any documents or articles to your file, 2 sir? 3 A. No. I mean -- I still don't 4 understand the question. Are you saying -- 5 as a scientist, I'll look at papers every 10:12 AM 6 day. So this report, when I prepared this, 7 it wasn't only the 500-plus references. 8 There's, like I said, other papers that I 9 didn't cite that I may read. 10 But as a scientist, I'm always 10:12 AM 11 learning every week and looking up the 12 latest -- my -- as a career, what I focus in 13 on, what causes cancer and mechanisms that we 14 can block cancer. 15 Q. Have there been any articles that 10:13 AM 16 have come to your attention since the time of 17 your report that are relevant to the question 18 at hand with regard to low-levels of NDMA or 19 NDEA and any risk of cancer? 20 A. Nothing comes to the mind since I 10:13 AM 21 prepared this report. 22 Q. It's your testimony that on a 23 nearly daily basis, as a scientist, that 24 you're out there looking for new information 25 and new articles to keep yourself up to date 10:13 AM</p>	<p style="text-align: right;">Page 52</p> <p>1 A. Yes, so I -- when -- of the 583 2 publications I went through and picked out 3 about 400 publications that I sent to 4 counsel. 5 Q. Okay. Thank you. 10:14 AM 6 Sir, during COVID, have you been 7 going into your office at the -- actually, 8 where is your office? Is it at a medical 9 school or at a hospital? 10 A. It's actually across from Fenway 10:15 AM 11 Park, where the Red Sox play. It's Beth 12 Israel Deaconess Medical Center, but we have 13 certain -- we have different branches, and 14 the one that I'm at is the research building 15 across from Fenway Park. 10:15 AM 16 Q. Cool. Have you been going into 17 work or going to the ball game? 18 A. Actually -- so we had to 19 completely shut the lab down back in 2020 20 from March till around June. And then after 10:15 AM 21 that, we reopened the lab. We actually could 22 only -- like, once a week, we had to go in to 23 make sure the mice are okay and certain 24 things like that. 25 But since then we've been pretty 10:15 AM</p>
<p style="text-align: right;">Page 51</p> <p>1 on things. 2 That's your testimony, right? 3 A. Right. 4 Q. And you've continued that process 5 since July of '21, when this report was 10:13 AM 6 submitted? 7 A. Correct. 8 Q. And it's your testimony that 9 nothing comes to mind that has been published 10 since July of '21 that's relevant to this 10:14 AM 11 litigation -- to the issues in this 12 litigation? I just want to be clear. 13 A. Correct. Correct. 14 MR. NIGH: Form objection. 15 MR. FOWLER: Thank you. 10:14 AM 16 THE WITNESS: Right. 17 BY MR. FOWLER: 18 Q. All right. Sir, with regard to 19 the documents that were provided on 20 September 7th, '21, which is marked as 10:14 AM 21 Exhibit 3, did you have any role in -- let 22 me -- let me start that again. 23 Did you assist counsel in 24 compiling the documents that were provided to 25 defense counsel? 10:14 AM</p>	<p style="text-align: right;">Page 53</p> <p>1 much up and running, obviously, with certain 2 restrictions. At some point we had to wear a 3 mask, so there were restrictions where -- a 4 certain number of people in a room, or you 5 had to eat -- a certain number of people 10:16 AM 6 eating lunch. But we basically opened the 7 lab last summer. 8 Q. Did the research that you did for 9 your report in this case -- did you do that 10 sitting in your lab office or in your home 10:16 AM 11 office? 12 MR. NIGH: Form objection. 13 A. So I would say both. During 14 COVID, though, I was working a lot from home, 15 because part of the reason too is I live in 10:16 AM 16 the South Shore and anyone that knows Boston 17 before COVID, that 25 miles can take an hour 18 and a half. So one of the few advantages -- 19 or good things that happened with COVID is 20 the commute times went down. 10:16 AM 21 So because I have a lab -- I 22 supervise a couple scientists, postdocs, and 23 research assistants, so we only have to meet 24 maybe once a week or once every two weeks, 25 something like that. 10:17 AM</p>

<p style="text-align: right;">Page 54</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. Yes, sir. You testified that you</p> <p>3 did receive Dr. Chodosh's report?</p> <p>4 A. Yes.</p> <p>5 Q. And do you recall Dr. Chodosh is a 10:17 AM</p> <p>6 cancer cell biologist?</p> <p>7 A. Yes.</p> <p>8 Q. Which you hold yourself out to be</p> <p>9 as well?</p> <p>10 A. Yes. 10:17 AM</p> <p>11 Q. Had you -- were you familiar with</p> <p>12 Dr. Chodosh before seeing his report in this</p> <p>13 case?</p> <p>14 A. I haven't actually met him. I've</p> <p>15 read in the literature some of his papers, 10:17 AM</p> <p>16 and in the Actos case, I was familiar with</p> <p>17 some of his reports in that case.</p> <p>18 Q. Being familiar with that area of</p> <p>19 science, does Dr. Chodosh enjoy a strong</p> <p>20 reputation among cancer cell biologists? 10:17 AM</p> <p>21 A. Yes --</p> <p>22 MR. NIGH: Form -- form objection.</p> <p>23 A. I think he's a very well-respected</p> <p>24 scientist. I don't know him personally</p> <p>25 but... 10:17 AM</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. Generally, what did you disagree</p> <p>2 with?</p> <p>3 A. I would have to go through his</p> <p>4 report and go specifically -- statements in</p> <p>5 the report. 10:19 AM</p> <p>6 Q. Yes, sir, I understand.</p> <p>7 Now, if we -- if we could, let's</p> <p>8 turn our attention to Exhibit 2. It's your</p> <p>9 CV, sir, if you would like to put that in</p> <p>10 front of you. 10:19 AM</p> <p>11 It's a pretty long CV, not as long</p> <p>12 as your report, but let's see if we can -- we</p> <p>13 can get into it.</p> <p>14 Help me understand, please, fresh</p> <p>15 question, what is your current position, sir? 10:19 AM</p> <p>16 A. Yes, it's assistant professor of</p> <p>17 pathology. It should be -- yeah, it's right</p> <p>18 at the bottom of the first page, where it</p> <p>19 says 2014 with a dash, assistant professor of</p> <p>20 pathology. 10:20 AM</p> <p>21 Q. Okay. And you have listed Harvard</p> <p>22 Medical School, correct?</p> <p>23 A. Correct.</p> <p>24 Q. Now, does Harvard Medical School</p> <p>25 appear on your paycheck, or is it something 10:20 AM</p>
<p style="text-align: right;">Page 55</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. And he works out of a University</p> <p>3 of Pennsylvania laboratory?</p> <p>4 A. Correct.</p> <p>5 Q. And that's a reputable lab? 10:17 AM</p> <p>6 A. Yeah, that's an excellent place,</p> <p>7 yeah.</p> <p>8 Q. Was there anything in</p> <p>9 Dr. Chodosh's report that you disagreed with?</p> <p>10 MR. NIGH: Form objection. 10:18 AM</p> <p>11 A. I have to say I focused -- I</p> <p>12 didn't spend much time on -- I may have read</p> <p>13 his report once or twice. I focus on my</p> <p>14 opinions and my report.</p> <p>15 BY MR. FOWLER: 10:18 AM</p> <p>16 Q. Right. Dr. Chodosh's report was</p> <p>17 provided in August of '21, a month after</p> <p>18 yours. You're aware of that, right?</p> <p>19 A. Right.</p> <p>20 Q. So your report was already 10:18 AM</p> <p>21 completed when you read Dr. Chodosh's report.</p> <p>22 Again, my question is, was there anything</p> <p>23 that you disagreed with?</p> <p>24 A. Yes, but -- just in thinking about</p> <p>25 it generally, I can't comment on specifics. 10:18 AM</p>	<p style="text-align: right;">Page 57</p> <p>1 else?</p> <p>2 A. Harvard Medical School -- no,</p> <p>3 Beth -- the answer is Beth Israel Deaconess</p> <p>4 Medical Center.</p> <p>5 Q. Yes, sir. 10:20 AM</p> <p>6 A. The faculty appointment goes</p> <p>7 through Harvard Medical School, so that's why</p> <p>8 it says Harvard Medical School.</p> <p>9 Q. Right. And in your position at</p> <p>10 Beth Israel Deaconess Hospital, you 10:20 AM</p> <p>11 automatically get a faculty appointment at</p> <p>12 the Harvard Medical School; isn't that</p> <p>13 correct?</p> <p>14 A. Actually, no, that's not correct.</p> <p>15 What happens is, you can be an 10:20 AM</p> <p>16 employee of Beth Israel Deaconess Medical</p> <p>17 Center, but to become a faculty member</p> <p>18 through Harvard Medical School -- Harvard</p> <p>19 Medical School has five different hospitals,</p> <p>20 so Beth Israel is just one of them, 10:21 AM</p> <p>21 Dana-Farber, Children's, Brigham, MGH.</p> <p>22 To get a faculty appointment at</p> <p>23 Beth Israel Deaconess Medical Center, because</p> <p>24 it's a hospital, they don't confer it. You</p> <p>25 have to go through Harvard Medical School. 10:21 AM</p>

<p style="text-align: right;">Page 58</p> <p>1 So it's just affiliated with Harvard Medical 2 School. 3 Q. Do you have to go through Harvard 4 Medical School, or is that part and parcel to 5 being hired at Beth Israel Deaconess in your 10:21 AM 6 department? 7 MR. NIGH: Form objection. 8 A. So because I was hired as an 9 assistant professor of pathology back in 10 2014, it went through Harvard Medical School 10:21 AM 11 and Beth Israel. 12 BY MR. FOWLER: 13 Q. Isn't it true, Doctor, that in 14 2011, prior to your appointment, the 15 Department of Pathology at Harvard was 10:21 AM 16 restructured such that its faculty are solely 17 comprised of faculty from the four 18 departments of pathology at the large Harvard 19 academic medical centers of which Beth Israel 20 Deaconess is one? 10:22 AM 21 A. There's movements all the time 22 between Mass General and Brigham and certain 23 other Harvard hospitals. 24 When I was hired in 2014 -- I was 25 at Children's Hospital before that -- I was 10:22 AM</p>	<p style="text-align: right;">Page 60</p> <p>1 Harvard University Medical School, correct? 2 A. Correct. 3 Q. Have you discussed your theories 4 that are set forth and your opinions that are 5 set forth in your report with any other 10:23 AM 6 Harvard University Medical School physician? 7 A. No. 8 Q. No one -- so it follows that no 9 one else at Harvard University Medical School 10 has said to you, I agree with your opinions? 10:24 AM 11 A. Correct. 12 Q. And your report is not peer 13 reviewed? 14 A. Correct, this is not published. 15 Q. Yes, sir. 10:24 AM 16 And you don't contend that if you 17 submitted that as a manuscript, that it would 18 ever be accepted as a peer -- in a 19 peer-review process? 20 Let me rephrase the question. 10:24 AM 21 Do you believe that your report 22 would pass peer review in an accredited 23 journal? 24 A. So when you submit a paper to -- 25 no, this isn't written for a -- when you 10:24 AM</p>
<p style="text-align: right;">Page 59</p> <p>1 hired through Beth Israel Deaconess Medical 2 School and the pathology department. 3 Q. Isn't it true that any faculty 4 member hired in a department of pathology at 5 one of those four hospitals, automatically 10:22 AM 6 becomes an assistant professor at Harvard? 7 A. No, that's not true. You have to 8 go through a process of becoming -- getting 9 promoted to assistant professor of pathology. 10 Q. When you came -- okay. I'll come 10:22 AM 11 back to that. 12 Do you have a faculty appointment 13 in any basic science department at Harvard? 14 A. Just this appointment. 15 Q. Did you let Harvard University 10:23 AM 16 Medical School know that you are involved in 17 this litigation? 18 A. So I haven't signed a contract 19 with anyone. I can consult independently. I 20 don't -- I'm not under any contract to let 10:23 AM 21 them know. 22 Q. So that's another way of saying 23 no, you did not let Harvard know that you are 24 involved in this case, that you're testifying 25 in this case; you never informed anybody at 10:23 AM</p>	<p style="text-align: right;">Page 61</p> <p>1 submit a paper to a journal, usually you pick 2 a certain journal and they have a certain 3 format you follow, and this doesn't follow 4 the format of most of the journals we would 5 submit to. 10:25 AM 6 But the scientific process of how 7 this is written and my scientific process of 8 determining -- answering the question, does 9 NDMA or NDEA cause cancer, that scientific 10 process is very similar to publications we 10:25 AM 11 would write. 12 Q. Yes, sir. 13 Now, sir, looking at your CV, 14 let's look under education. If I understand 15 correctly from your previous testimony, you 10:25 AM 16 were accepted right out of high school into 17 an accelerated bachelor's of science MD 18 program at Boston University? 19 A. Correct. 20 Q. What year were you in high school 10:26 AM 21 when that happened? 22 A. 1985. There are certain programs 23 where -- normally, to get into medical 24 school, what most people do is you do four 25 years of college, and you either apply 10:26 AM</p>

<p style="text-align: right;">Page 62</p> <p>1 directly after college or you take a couple 2 gap years, and then you go to medical school. 3 If you really know you want to be 4 a doctor at a young age in the United States, 5 there's a couple programs coming out of high 10:26 AM 6 school where you can go directly into a 7 program. You still do college and medical 8 school. But the big advantage is you don't 9 have take the MCATs, and you're already into 10 medical school, assuming you keep your grades 10:26 AM 11 up. And that, I did. So Boston University 12 had a program. 13 I actually got into University of 14 Miami's program, and my parents wanted me to 15 come to Boston, even though I wanted to go to 10:26 AM 16 Miami. 17 And -- yeah, so there's other 18 programs in the country where, if you decide 19 you want to go to medical school at a very 20 young age, you know you can do that. 10:26 AM 21 Q. So your high school graduation 22 year would be 1985? 23 A. Yes. 24 Q. Same here. Okay. Good job. 25 And so that was an accelerated 10:27 AM</p>	<p style="text-align: right;">Page 64</p> <p>1 medical degree? 2 A. Yes, I got it in '94, yes, yes. 3 I ended up doing an extra year. I 4 was a swimmer in college too, so I ended up, 5 even though I was in the medical program, 10:28 AM 6 also swimming. So I did that for an extra 7 year. I was -- and then -- and like I said 8 before, I fell into Folkman lab. So I took a 9 extra year of full-time cancer research, and 10 that's where I really, you know, got into 10:28 AM 11 cancer research, and that's kind of been the 12 passion for me, you know. 13 Q. Uh-huh. So you're testifying 14 that, you know, in that break between 15 undergrad and med school you worked at 10:29 AM 16 Dr. Folkner's [sic] lab as some sort of 17 research assistant for a couple years? 18 A. Yes, yes. Dr. Folkman was -- he 19 was -- should have won the Nobel Prize. He 20 pioneered this whole field of angiogenesis, 10:29 AM 21 and it was a very exciting time in the lab. 22 Q. And it's your testimony, in that 23 first experience, that's where you really 24 fell in love with cancer research and 25 developed your passion for that? 10:29 AM</p>
<p style="text-align: right;">Page 63</p> <p>1 program, the complete undergrad and medical 2 school in six years? 3 A. Yeah, at the time when I was doing 4 it, it was six years, but I ended up 5 taking -- you had options to do it in six, 10:27 AM 6 seven, or eight. The six-year part, you had 7 to go over four summers, and I ended 8 falling -- and that's how I fell into cancer 9 research, into Judah Folkman's lab in 1989. 10 And so I spent an extra year or two in the 10:27 AM 11 lab. 12 So I ended up that program -- I 13 ended up doing it, like, in eight years. I 14 didn't do the six years because I ended up 15 really loving the lab. So I spent some time 10:27 AM 16 in Dr. Folkman's lab. 17 Q. Did you -- as part of this 18 acceptance into the program, did you get a 19 full-ride scholarship as part of that? 20 A. Unfortunately, no. Boston 10:27 AM 21 University is very expensive, and there's no 22 academic scholarships or, you know.. 23 Q. And if I understand your CV 24 correctly, it actually took nine years before 25 you got your degree; is that correct -- your 10:28 AM</p>	<p style="text-align: right;">Page 65</p> <p>1 A. Correct. 2 Q. And so you went into med school 3 with that experience behind you and that 4 passion in your heart for that sort of work? 5 A. Correct. Correct. And that's -- 10:29 AM 6 that's actually one of the -- going through 7 med school, even though you learn the 8 diseases and different, you know, 9 pathologies, having that scientific 10 background really -- to be able to bring from 10:30 AM 11 the bench to the bedside, you know, the 12 discoveries we make in the lab, that's been 13 very exciting. And that's been -- we've been 14 able to translate a couple drugs that we 15 discovered ourselves in the lab into cancer 10:30 AM 16 patients currently, so.. 17 Q. And so when you went to med school 18 after that experience, come fourth year, you 19 have -- what would be the fourth year, you 20 understand -- you have to go through a 10:30 AM 21 residency matching program, right? 22 A. Yes. 23 Q. And in that matching program, you 24 have to designate departments and medical 25 schools where you want to do your residency, 10:30 AM</p>

<p style="text-align: right;">Page 66</p> <p>1 and you rank them, correct?</p> <p>2 A. Correct.</p> <p>3 Q. And you provide approximately five</p> <p>4 choices because you don't know where you're</p> <p>5 going to end up? 10:30 AM</p> <p>6 A. Correct.</p> <p>7 Q. And then -- is it black Tuesday,</p> <p>8 right? That's what they say?</p> <p>9 A. Yeah, it used to be a mailbox day.</p> <p>10 Now -- these days, they get it by email. 10:30 AM</p> <p>11 Yeah, it's either on a Wednesday or a</p> <p>12 Tuesday. It's in mid-March.</p> <p>13 Q. Right.</p> <p>14 A. And that's -- you kind of know</p> <p>15 where you're going to spend the next part of 10:31 AM</p> <p>16 your lives.</p> <p>17 And for me, it was actually -- the</p> <p>18 reason I ended up in New Jersey, Robert Wood</p> <p>19 Johnson, is my wife, who, at the time -- we</p> <p>20 met over a cadaver first-year med school. We 10:31 AM</p> <p>21 ended up doing a couples match and she had</p> <p>22 matched for the New Jersey program which --</p> <p>23 and it matches as a couple.</p> <p>24 Q. I understand.</p> <p>25 A. And so that's how I ended up -- 10:31 AM</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. And when you went to --</p> <p>2 A. I would -- I would just say the</p> <p>3 reason for that -- I don't know if you want</p> <p>4 me to get into that. But the reason for that</p> <p>5 is my mentors at the time were surgeons, and 10:32 AM</p> <p>6 a big influence at that time in my life was</p> <p>7 Roger Jenkins, and he did the first liver</p> <p>8 transplant in Boston. I spent four years</p> <p>9 with him from 1990 to '94, and I was going</p> <p>10 to -- basically, I wanted to pursue liver 10:32 AM</p> <p>11 transplant as a -- as a career.</p> <p>12 Q. I see. You wanted to pursue liver</p> <p>13 transplant, not cancer research that was your</p> <p>14 passion for the two years in between med</p> <p>15 school and college. 10:32 AM</p> <p>16 A. Well -- right. My goal was to be</p> <p>17 a surgeon-scientist, kind of -- which is what</p> <p>18 Dr. Folkman was. He was a surgeon-scientist.</p> <p>19 Q. Okay.</p> <p>20 A. And in retrospect, I probably 10:32 AM</p> <p>21 should have just gone into pathology because</p> <p>22 you don't have a lot of hours in surgery to</p> <p>23 do researches. The hours are very long.</p> <p>24 Q. Yes, sir. And as a first-year</p> <p>25 surgical resident, your technically -- they 10:32 AM</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. Okay. And you -- the match that</p> <p>2 you were going after was a surgical</p> <p>3 residency?</p> <p>4 A. Correct.</p> <p>5 Q. And you would have applied for a 10:31 AM</p> <p>6 surgical -- and a general surgical residency</p> <p>7 is what it is, right?</p> <p>8 A. Correct.</p> <p>9 Q. And that's one of the most</p> <p>10 competitive, correct? 10:31 AM</p> <p>11 A. Correct.</p> <p>12 Q. And you would have applied for a</p> <p>13 general surgical residency in multiple</p> <p>14 programs, right?</p> <p>15 A. Right. 10:31 AM</p> <p>16 Q. You did not apply for a pathology</p> <p>17 residency?</p> <p>18 A. Correct.</p> <p>19 Q. That's -- that was available to</p> <p>20 you? 10:31 AM</p> <p>21 A. Correct.</p> <p>22 Q. And following your work in</p> <p>23 Faulkner's [sic] -- Dr. Faulkner's lab, you</p> <p>24 elected to pursue surgery?</p> <p>25 A. Correct. 10:32 AM</p>	<p style="text-align: right;">Page 69</p> <p>1 will call it an intern, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Did you wear the short, white</p> <p>4 jackets traditionally?</p> <p>5 A. Yeah, yeah. 10:33 AM</p> <p>6 Q. Yes, sir.</p> <p>7 And in your second year in a</p> <p>8 surgical residency program, that is your</p> <p>9 rotation year, correct?</p> <p>10 A. Well, yeah, you do rotations in 10:33 AM</p> <p>11 the first year and the second year. The</p> <p>12 first year, you're -- as an intern, you're a</p> <p>13 lot of times in the hospital doing all the</p> <p>14 scut work. And then second year, you're in</p> <p>15 the operating room a little bit more. 10:33 AM</p> <p>16 Q. Right. And the second year at</p> <p>17 your residency program was a rotation year</p> <p>18 where you'd go to pediatric surgery, correct?</p> <p>19 A. Well, we actually, in our</p> <p>20 particular program, rotated also first year. 10:33 AM</p> <p>21 Like, even in the first year, we -- but, yes,</p> <p>22 you're right. We do different -- like,</p> <p>23 you'll do neurosurgery one month and do</p> <p>24 orthopedic surgery.</p> <p>25 Q. Yes, sir. That's where I was -- I 10:33 AM</p>

<p style="text-align: right;">Page 70</p> <p>1 was going. And your second year, your 2 rotations included pediatric, orthopedic, 3 neurosurgery, but not oncology surgery. 4 There's not an oncology surgery 5 rotation at UMDJ [sic] is there? 10:34 AM 6 A. Usually -- there is a -- oncology 7 department and the -- 8 Q. Yes. 9 A. -- surgery, but usually, the 10 senior residents are more in that -- 10:34 AM 11 Q. That's right. 12 A. -- they'll do -- the cancer 13 surgeries are more -- that's a more 14 complicated surgery, so it's more the senior 15 residents are doing it. 10:34 AM 16 Q. I understand. 17 In the second-year rotation -- let 18 me start again. 19 In the second-year surgery 20 residency, you are, in one way to look at it, 10:34 AM 21 trying out different types of surgeries, 22 because then come third year, you get more of 23 an election on where you want additional 24 training in those areas, correct? 25 MR. NIGH: Form objection. 10:34 AM</p>	<p style="text-align: right;">Page 72</p> <p>1 Q. I understand that. 2 A. Yeah. 3 Q. As a second-year resident, you are 4 not putting scalpel to skin, are you? 5 A. Correct, you're -- it's more 10:35 AM 6 assisting the attending surgeon. 7 Q. You failed to complete your 8 surgical residency, correct? 9 MR. NIGH: Form objection. 10 A. So after my second year, I was in 10:36 AM 11 a general surgery categorical program for 12 five years, but part of that program, you 13 have to do research. So because I had 14 already spent four years in Dr. Folkman's lab 15 as a medical student and as -- a full-time 10:36 AM 16 year as a college student, I already knew 17 that, for my research years, I wanted to go 18 back to Boston and do my research here in the 19 Folkman lab. So I already was planning that 20 ahead of time, so. 10:36 AM 21 BY MR. FOWLER: 22 Q. You were planning on doing two 23 years of a surgery resident; then leaving 24 surgery and going to a lab? 25 A. No, so originally the program is 10:36 AM</p>
<p style="text-align: right;">Page 71</p> <p>1 A. Correct, you can say that. 2 BY MR. FOWLER: 3 Q. And as a second-year -- 4 A. Well, really what it is is five 5 years of general surgery, and then you have 10:34 AM 6 to decide after that what type of surgery you 7 want to go into. 8 Q. If you're going to be a fellow or 9 a chief, right? 10 A. Yeah, it depends the program. 10:35 AM 11 Q. Yes, sir. I'll strike that. 12 As a second-year, you're not 13 likely cutting on patients, second-year 14 surgical resident, are you? 15 A. Oh, yeah, we're in the operating 10:35 AM 16 room. You do cases such as hernias and 17 breast biopsies and, you know, 18 laparoscopic -- you know, remove gall 19 bladders. You just don't do the more 20 advanced cases as a second-year resident. 10:35 AM 21 Q. As a second-year surgical 22 resident, it's your testimony you put scalpel 23 to skin and did an operation? 24 A. You're assisting the attending 25 surgeon. 10:35 AM</p>	<p style="text-align: right;">Page 73</p> <p>1 you have to do one or two years of research 2 as part of the program between your second 3 and third year of surgery. Everybody does -- 4 all the general surgery residents do their 5 research here. Some of them will stay in New 10:36 AM 6 Jersey and do it at Robert Wood. Some will 7 go elsewhere. And I went back to 8 Dr. Folkman's lab. 9 And when I went back as a -- as a 10 surgery resident, that's where I really 10:37 AM 11 realized that I loved cancer research more 12 than being a surgeon. 13 Q. Doctor, you were out of the 14 surgical residency program at UMDNJ as of 15 1996. You were no longer a surgical 10:37 AM 16 resident; isn't that correct? 17 A. Correct. 18 MR. NIGH: Form objection. 19 BY MR. FOWLER: 20 Q. You were out of the program 10:37 AM 21 completely. You didn't -- isn't that 22 correct? 23 A. Correct. 24 Q. You elected to pursue research, 25 not as part of your surgical residency, but 10:37 AM</p>

<p style="text-align: right;">Page 74</p> <p>1 as a -- as a new direction in your medical 2 career?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. Initially, I did think about going 5 back to surgery, but then when I was in the 10:37 AM 6 Folkman lab, I decided I wanted to stay in 7 the research lab.</p> <p>8 BY MR. FOWLER:</p> <p>9 Q. You were not able to turn around 10 after leaving your second-year surgical 10:38 AM 11 residency and coming to work for Boston's 12 children. It wasn't an option for you to go 13 back and resume a third year of surgical 14 residency at UMDJ [sic] was it?</p> <p>15 MR. NIGH: Form objection. 10:38 AM</p> <p>16 A. I didn't want to go back. I 17 wanted to -- that's where I switched careers. 18 I wanted to do cancer research.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. You spent your fourth year of 10:38 AM 21 medical school trying to match with a general 22 surgery program because you wanted to be a 23 surgeon, and you quit the program before ever 24 really getting to be a surgeon; isn't that 25 true? 10:38 AM</p>	<p style="text-align: right;">Page 76</p> <p>1 four-year residency at UMDJ?</p> <p>2 A. Yes.</p> <p>3 MR. NIGH: Form objection.</p> <p>4 BY MR. FOWLER:</p> <p>5 Q. So you left your wife and your 10:39 AM 6 residency program to come to Boston?</p> <p>7 A. Yes.</p> <p>8 Q. Because you wanted to?</p> <p>9 A. We were one year apart because she 10 had to complete her pediatric residency. 10:39 AM</p> <p>11 Q. Right.</p> <p>12 A. So for one year, she was in New 13 Jersey; I was in Boston, because my -- and 14 she totally supported it because my passion 15 was to be in Dr. Folkman's lab. 10:39 AM</p> <p>16 Q. Your passion led you to apply for 17 a couples residency program at UMDJ in the 18 Department of Surgery, sir; isn't that, 19 correct?</p> <p>20 A. Correct. 10:40 AM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 BY MR. FOWLER:</p> <p>23 Q. Let me -- let me withdraw the 24 question.</p> <p>25 You went to the effort of applying 10:40 AM</p>
<p style="text-align: right;">Page 75</p> <p>1 MR. NIGH: Form objection.</p> <p>2 A. The reason I --</p> <p>3 BY MR. FOWLER:</p> <p>4 Q. Can we answer and then explain, 5 please? 10:38 AM</p> <p>6 A. Yes. So I did leave the program 7 of general surgery at Robert Wood Johnson to 8 pursue cancer research, because my passion 9 was I wanted to help find a cure for cancer. 10 And to me, that was a more meaningful pursuit 10:38 AM 11 than doing surgery.</p> <p>12 So -- and also, at the time, in 13 my -- ideally, I wanted to do both, but I 14 realized that surgery has such long hours, 15 and to do the cancer research at the level 10:39 AM 16 of, like, in Dr. Folkman's lab, you have to 17 do it full-time to really pursue the 18 research.</p> <p>19 Q. Right. Well, you say Dr. Faulkner 20 was a surgeon first? 10:39 AM</p> <p>21 A. Yes.</p> <p>22 Q. And you were trying to follow in 23 his footsteps?</p> <p>24 A. Correct.</p> <p>25 Q. Did your wife complete her 10:39 AM</p>	<p style="text-align: right;">Page 77</p> <p>1 for a general surgery residency with your 2 wife, and you did not complete -- you failed 3 to complete the program. You left your wife 4 and the residency program. And I'm curious 5 as to why, sir. 10:40 AM</p> <p>6 A. Yeah --</p> <p>7 MR. NIGH: Hold on. Hold on. Let 8 me put my objection in. Form objection. 9 Go ahead.</p> <p>10 A. Yeah, so for me, and my wife 10:40 AM 11 totally supported this, is that I realized 12 initially when I was applying to general 13 surgery, I still want to do research and 14 cancer research. Sometimes in a career, you 15 realize -- you shift directions. 10:40 AM</p> <p>16 So after two years of surgery, I 17 realized, when I -- after that, when I was in 18 Dr. Folkman's lab, which -- this is a 19 potential Nobel Prize winning lab that 20 founded the field of angiogenesis. It was a 10:41 AM 21 20- to 30-person lab. This was like the -- 22 when the Patriots won six SuperBowls. This 23 is Judah Folkman's angiogenesis lab back -- 24 you know, he pioneered the concept in 1971 of 25 angiogenesis, and he was a father figure to 10:41 AM</p>

<p style="text-align: right;">Page 78</p> <p>1 many of us, and it was just a very special 2 place. 3 I actually probably would have 4 matched in Boston, but my wife had matched in 5 New Jersey, and the couples match took us to 10:41 AM 6 New Jersey, which I actually went to high 7 school and grew up in New Jersey. 8 So my wife's pediatric program, 9 she had to finish one more year. So she 10 stayed in New Jersey. And my passion, after 10:41 AM 11 doing two years of surgery, I very much 12 wanted to go back to Dr. Folkman's lab for my 13 research, and that's where I realized -- I 14 weighed how much I enjoy -- or passion of 15 cancer research versus being a surgery 10:42 AM 16 resident. 17 And for me it was -- that one year 18 apart, which, you know, that's where 19 sometimes couples are apart for a year for 20 their careers, and also -- my wife also is 10:42 AM 21 from the Boston, South Shore area, so she 22 knew that she was coming back to 23 Massachusetts after her pediatrics program. 24 So New Jersey was only -- we were only going 25 to be there to finish the residencies. 10:42 AM</p>	<p style="text-align: right;">Page 80</p> <p>1 to pursue the research because I knew that's 2 what I wanted to do. I mean, that's what -- 3 there are many scientists who decide -- they 4 may have been trained as a clinician, but 5 then, they decide they want to pursue science 10:43 AM 6 full-time, and that's what I decided. 7 BY MR. FOWLER: 8 Q. So you didn't attempt to join any 9 relevant residency program to cancer research 10 when you left New Jersey. You came straight 10:44 AM 11 to the lab as a research fellow? 12 A. Yes. 13 Q. You are not -- you completed 14 medical school, but you're not a licensed 15 physician, correct? 10:44 AM 16 A. Correct. 17 Q. You are not board certified in 18 anything; isn't that true? 19 A. Correct. 20 Q. You are not board eligible to take 10:44 AM 21 any board; isn't that true? 22 A. Correct. 23 Q. You completed no residency -- 24 strike that question. 25 Sir, you have never laid hands on 10:44 AM</p>
<p style="text-align: right;">Page 79</p> <p>1 And then, she totally supported me 2 going back to the lab. And that's where my 3 passion for the past 30 years -- since 1989, 4 when I was in the Judah Folkman lab, so over 5 30 years of cancer research, except for the 10:42 AM 6 two years I was doing surgical residency and 7 the four years of medical school. It was 8 pretty much full-time. 9 And when I came back to 10 Dr. Folkman's lab in '96, I came as a surgery 10:42 AM 11 resident, but I decided to stay as a -- as a 12 research fellow. So I wasn't a surgery 13 resident anymore at New Jersey. I was a 14 research fellow at Children's Hospital and 15 then, I became, basically, an instructor. So 10:43 AM 16 I want from a fellow to instructor. 17 BY MR. FOWLER: 18 Q. Doctor, when you came in 1996 to 19 return to Dr. #Faulkner's lab, when you 20 walked in that door, you were not a surgical 10:43 AM 21 resident. You just said you came there as a 22 surgical resident. That's not true, is it, 23 Doctor? You were out of the program? 24 MR. NIGH: Form objection. 25 A. Well, I left the program to do -- 10:43 AM</p>	<p style="text-align: right;">Page 81</p> <p>1 a patient since leaving the New Jersey 2 residency program; isn't that true? 3 A. Correct, I have -- correct. 4 Q. You have never diagnosed a patient 5 with cancer? 10:45 AM 6 A. I collaborate with many 7 oncologists for the last 30 years to bring a 8 cancer drug to the clinic. I work very 9 closely with oncologists, and the scientific 10 process of translating a cancer drug to the 10:45 AM 11 clinic involves, by necessity, I work with 12 multiple oncologists, very closely. 13 Sometimes, we would have lab 14 meetings once or twice a week where -- at 15 Beth Israel Deaconess, we meet with 10:45 AM 16 Dana-Farber oncologists. And one of my 17 mentors is Dr. Mark Kieran, and he was 18 director of pediatric neuro-oncology. 19 So while I myself didn't treat the 20 patients, we would have a lot of intertumor 10:45 AM 21 and board meetings and discuss patients and 22 learning the clinical side. 23 Q. You have no patient 24 responsibility -- let me -- let me start that 25 again. 10:46 AM</p>

<p style="text-align: right;">Page 82</p> <p>1 As part of your work, you do not</p> <p>2 read patient slides as a pathologist, do you?</p> <p>3 A. Correct.</p> <p>4 Q. Because you're not a pathologist?</p> <p>5 A. Correct. I'm a -- yeah. 10:46 AM</p> <p>6 Q. Since medical school and your</p> <p>7 two-year partial surgical residency program,</p> <p>8 you have had no additional education,</p> <p>9 correct?</p> <p>10 A. That's very misleading to say. We 10:46 AM</p> <p>11 use pathology all the time in cancer</p> <p>12 research. I view slides. I study them. I</p> <p>13 bring them to a pathologist, a</p> <p>14 board-certified pathologist, once a month.</p> <p>15 So we have to learn the process of 10:46 AM</p> <p>16 pathology, and going to medical school for</p> <p>17 four years taught me pathophysiology of</p> <p>18 disease, and two years of surgery, you learn,</p> <p>19 in the operating room, certain diseases. And</p> <p>20 so the process of pathology -- for example, 10:47 AM</p> <p>21 we use it every day in the lab, where we</p> <p>22 study murine tumors, for example, and we take</p> <p>23 it to a pathologist.</p> <p>24 So we're still studying pathology.</p> <p>25 It's just not -- and actually, we do study 10:47 AM</p>	<p style="text-align: right;">Page 84</p> <p>1 In 2007, I'll give an example, we</p> <p>2 had a drug that was a PPR alpha antagonist --</p> <p>3 THE REPORTER: We have a drug</p> <p>4 what?</p> <p>5 THE WITNESS: It's a PPR alpha 10:48 AM</p> <p>6 antagonist. And we published a</p> <p>7 publication. And then -- and a</p> <p>8 pharmaceutical company called Tempest,</p> <p>9 which was originally Inception,</p> <p>10 translated this drug into the clinic, 10:48 AM</p> <p>11 and it's currently in clinical trials</p> <p>12 for pancreatic cancer patients and it's</p> <p>13 being combined with immunotherapy.</p> <p>14 That process of translating that</p> <p>15 drug from 2007 to currently, 2021, which 10:49 AM</p> <p>16 I'm still working with industry to do,</p> <p>17 involves very much human modeling of</p> <p>18 cancer in animals and in people.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. As part of your work, you are 10:49 AM</p> <p>21 never responsible for reading a pathology</p> <p>22 slide and making the determination as to the</p> <p>23 cause of any cancerous cells that you might</p> <p>24 see under that slide, correct?</p> <p>25 MR. NIGH: Form objection. 10:49 AM</p>
<p style="text-align: right;">Page 83</p> <p>1 human cancers in our publication. So we do</p> <p>2 get sections from -- commercially available</p> <p>3 and study similar processes that a</p> <p>4 pathologist would look at in clinical</p> <p>5 patients. 10:47 AM</p> <p>6 Q. Yes, sir. My question was, since</p> <p>7 medical school, you've had no additional</p> <p>8 formal education in pathology, correct?</p> <p>9 MR. NIGH: Hold on. Form</p> <p>10 objection. That wasn't your prior 10:47 AM</p> <p>11 question. But you can answer.</p> <p>12 A. That's not correct. We have</p> <p>13 pathology grand rounds. We have pathology</p> <p>14 research rounds. We have pathology clinical</p> <p>15 rounds. Beth Israel Deaconess Medical Center 10:47 AM</p> <p>16 is a world famous place. So we -- I hear</p> <p>17 plenty of clinicians come and give talks on</p> <p>18 updating recent clinical topics, pathology</p> <p>19 topics, and then, as a research scientist,</p> <p>20 I'm always learning. 10:48 AM</p> <p>21 And what's important to realize is</p> <p>22 that, as a cancer scientist, we're --</p> <p>23 ultimate goal is to translate our discovery</p> <p>24 into the clinic in human patients, and that's</p> <p>25 what we did. 10:48 AM</p>	<p style="text-align: right;">Page 85</p> <p>1 A. In the context of -- in our cancer</p> <p>2 models, we do that all the time. We'll grow</p> <p>3 a tumor in animals, give it a drug, and then</p> <p>4 study the -- in my report, I talked about the</p> <p>5 10 key characteristics, immunosuppression, 10:49 AM</p> <p>6 chronic inflammation, angiogenesis, cell</p> <p>7 death.</p> <p>8 So those processes, we will -- one</p> <p>9 of the readouts is looking at a slide under</p> <p>10 the microscope, for example, angiogenesis is 10:50 AM</p> <p>11 blood vessel formation. So we will take</p> <p>12 those slides from our lab in the different</p> <p>13 cancer models and show it to a pathologist</p> <p>14 and try to understand, did the drug block</p> <p>15 cancer through a certain process. 10:50 AM</p> <p>16 BY MR. FOWLER:</p> <p>17 Q. So you'd go to a pathologist to</p> <p>18 learn what may or may not have caused what</p> <p>19 you're seeing under the slide?</p> <p>20 MR. NIGH: Form objection. 10:50 AM</p> <p>21 A. So as a scientist, I will have my</p> <p>22 own learning and view, but part of the</p> <p>23 process is working with experts in a</p> <p>24 particular field. So I would go to a</p> <p>25 clinical pathologist who has looked at 10:50 AM</p>

<p style="text-align: right;">Page 86</p> <p>1 different -- if we're studying blood vessel 2 tumors, so I'm going to a lymphoma 3 pathologist, for example, and then get their 4 opinion. 5 But I still will do my own 10:51 AM 6 research and study -- look at slides under 7 the microscope ourselves and my colleagues, 8 but then, we like to go to somebody who's 9 like a board-certified clinician, and just to 10 get their feedback. 10:51 AM 11 But then -- part of science has 12 become very interdisciplinary. So my 13 specialty has been cancer modeling, modeling 14 human cancer in animals, studying the 15 mechanisms of what causes cancer and 10:51 AM 16 translating drugs from the clinic to cancer 17 patients. 18 So part of science is working with 19 other experts in a particular field so we 20 synergize the discoveries. 10:51 AM 21 BY MR. FOWLER: 22 Q. Nothing in your work, on a 23 day-to-day basis, over the past X number of 24 years since you left your surgical residency 25 program -- none of your work involves 10:52 AM</p>	<p style="text-align: right;">Page 88</p> <p>1 We'll take their tumor and grow it in 2 culture, and then put it into mice, and we 3 study the mechanisms of cancer causation with 4 that human tumor. 5 Q. And the part of what you've just 10:53 AM 6 said, when you receive a tumor that's come 7 from an actual patient, a malignant tumor 8 that's been removed and ends up -- some part 9 of it in your lab, you are not able to look 10 at that tumor and make any determination what 10:53 AM 11 caused that cancer, correct? 12 MR. NIGH: Form objection. 13 A. I can look at the tumor and look 14 at, for example -- well, what caused the 15 cancer depends on the patient. What I look 10:54 AM 16 at under the microscope -- for example, 17 inflammation, I can look at a slide under the 18 microscope from a patient -- from a patient 19 that -- we got from the patient, grew it in 20 the mice, and then, we get a section. It's 10:54 AM 21 called hematoxylin and eosin, H&E section. 22 I can look myself under a 23 microscope, and even though I'm not a 24 board-certified pathologist, I can say that's 25 a blood vessel, that's a macrophage, that's a 10:54 AM</p>
<p style="text-align: right;">Page 87</p> <p>1 diagnosing cancer in a human being, correct? 2 MR. NIGH: Form objection. 3 A. Correct. 4 BY MR. FOWLER: 5 Q. None of your work involves 10:52 AM 6 diagnosing the cause of cancer on a pathology 7 slide from a human patient, correct? 8 A. So as I mentioned before -- so 9 part of the key characteristics for human 10 relevance and human cells is you will take -- 10:52 AM 11 for example, relevant to this case, Parsa, 12 1981, took human pancreatic -- human 13 pancreatic cells, put them in culture -- this 14 is what we do all the time in the lab. We 15 take a human patient tumor, grind up the 10:52 AM 16 tumor, grow it in culture, and then add a 17 chemical or a carcinogen, and then inject 18 into mice. 19 And that's what Parsa did in 1981, 20 grew the human pancreas cancer cells, gave 10:53 AM 21 NDMA, and put it into immunocompromised mice 22 and grow tumors. 23 So that, we do all the time. We 24 take tumors from human cancer patients who 25 have surgery and their cancer is removed. 10:53 AM</p>	<p style="text-align: right;">Page 89</p> <p>1 neutrophil, the basics, because that's -- 2 over the last 20 years, I've learned working 3 with other pathologists. 4 And so part of the mechanisms of 5 what we do and what's relevant to here, is we 10:54 AM 6 take animal models, tumor models, and look at 7 it under microscope and look for the 8 inflammation, the angiogenesis, and the cell 9 death. 10 One of the big themes of our lab 10:54 AM 11 is that cell death, that apoptotic cell 12 death, can paradoxically stimulate tumor 13 growth. So we stain with certain markers in 14 the lab, and we look at it under microscope, 15 and for that, I can do that myself. 10:55 AM 16 BY MR. FOWLER: 17 Q. Doctor, my question was simply 18 this: When you receive that pancreatic tumor 19 cells, you cannot determine what caused it? 20 Yes or no, sir. 10:55 AM 21 MR. NIGH: Form objection. 22 A. I don't understand the question. 23 What caused -- 24 BY MR. FOWLER: 25 Q. You can't look at a pathology 10:55 AM</p>

<p style="text-align: right;">Page 90</p> <p>1 slide and say, this cancer was caused by 2 cigarette smoking; this cancer was caused by 3 family hereditary; and you can't say this 4 cancer was caused by NDMA. 5 There's no marker on the pathology 10:55 AM 6 slides that you're able to discern to make 7 that conclusion; isn't that correct? 8 MR. NIGH: Form objection. 9 A. So in Parsa 1981, that paper, they 10 grew -- they took a pancreas tumor from a 10:56 AM 11 patient, grew it in culture, added NDMA for a 12 couple weeks, and then put that into the 13 mice. Those pancreas -- actually, that was a 14 pancreas. It wasn't a pancreas cancer. It 15 was a pancreas. 10:56 AM 16 Those cells would not grow on 17 their own into a tumor. So when they expose 18 it to NDMA, they made the conclusion, 19 correctly, that the NDMA caused the pancreas 20 cancer. Because in that case, they took a 10:56 AM 21 pancreas tissue that wasn't a tumor, that 22 would normally not cause a tumor. 23 A normal cell, when you inject 24 into animals, won't cause a tumor. So in 25 that case, they gave the NDMA, and what would 10:56 AM</p>	<p style="text-align: right;">Page 92</p> <p>1 BY MR. FOWLER: 2 Q. Are you able to look at a 3 pathology slide from an actual human 4 cancerous tumor that ends up under your 5 microscope and determine what caused it, sir? 10:57 AM 6 A. No, we would need more 7 information. 8 Q. And, Doctor, isn't it true that 9 you're not aware of any publication that has 10 identified any hallmarks of pathology that 10:58 AM 11 would enable any pathologist to say that a 12 particular tumor is caused by NDMA? 13 A. So -- 14 Q. Please yes or no, and then 15 explain. 10:58 AM 16 A. Okay. Can you say that one more 17 time? I think that -- yeah. 18 Q. Doctor, are you able to look at a 19 pathology slide from an actual humor -- an 20 actual human malignant tumor that ends up 10:58 AM 21 under your microscope -- actually, I was 22 reading the wrong question. That's why I 23 hate real-time. Let me try it again. 24 Doctor, there's no publication 25 that you've ever seen that identifies any 10:58 AM</p>
<p style="text-align: right;">Page 91</p> <p>1 normally not cause a tumor in a mouse grew 2 into a tumor. 3 MR. FOWLER: Counsel, I believe 4 I'm entitled to yes-or-no answer, and he 5 can explain. So I'm going to ask the 10:57 AM 6 question one more time. 7 BY MR. FOWLER: 8 Q. Doctor, if you look at a slide 9 from a human tumor that's been removed from a 10 liver, a pancreas, or anything else, you, 10:57 AM 11 Dr. Panigrahy, are not able to look at that 12 slide and determine what caused that human's 13 cancerous tumor that you're looking at under 14 the slide? Yes or no, sir. 15 MR. NIGH: Hold on. Form 10:57 AM 16 objection. Just realized that's not 17 what your prior question was. 18 MR. FOWLER: I'm trying to make it 19 as crystal clear -- I'm not repeating my 20 question, Counsel. I'm trying to make 10:57 AM 21 it more clear, and I'm asking for a yes 22 or no, and then if there's more to it -- 23 but I'd like a yes or no. 24 Let me get a fresh question 25 here. 10:57 AM</p>	<p style="text-align: right;">Page 93</p> <p>1 kind of hallmark or identifying factor that 2 would allow a pathologist to determine a 3 tumor was caused by NDMA? 4 A. Correct. However, I'll say 5 causation is what we study in the lab. The 10:59 AM 6 pathologist doesn't determine causation. To 7 do causation in cancer, the standard assay is 8 called a chemical carcinogenesis bioassay. 9 (Reporter clarification.) 10 THE WITNESS: Chemical 10:59 AM 11 carcinogenesis bioassay. 12 THE WITNESS: And that's the assay 13 where you subject rodents -- usually, it 14 could be one or two years -- to a 15 chemical, and that's how you determine 10:59 AM 16 causation, and that's one of the very 17 important models to determine 18 causation. 19 BY MR. FOWLER: 20 Q. In your report, you refer to 10:59 AM 21 NDMA-induced cancer in humans. There's no 22 such diagnosis, is there, Doctor? 23 MR. NIGH: Form objection. 24 A. So -- correct. However, the 25 reason we can say NDMA is a human carcinogen 11:00 AM</p>

<p style="text-align: right;">Page 94</p> <p>1 or likely a human carcinogen is because</p> <p>2 there's abundant evidence of NDMA in people.</p> <p>3 And I'll just mention a couple studies that</p> <p>4 come off to -- in mind. 1934, Friend --</p> <p>5 Freund, F-r-e-u-n-d, had shown -- it was -- 11:00 AM</p> <p>6 unfortunately, these are poisoning cases or</p> <p>7 unfortunate exposure, and they were exposed</p> <p>8 to NDMA, and they died from liver problems,</p> <p>9 like acute hepatitis toxicity. And then</p> <p>10 1980, one of the classic papers, Herrin and 11:00 AM</p> <p>11 Shank, a 1980 cancer research, and there's</p> <p>12 unfortunate poisoning with NDMA, and what was</p> <p>13 very informative and very important for human</p> <p>14 relevance is that the liver in the human who</p> <p>15 died from the NDMA had high amounts of the 11:01 AM</p> <p>16 DNA adducts called N7-methylguanine,</p> <p>17 O-6-methylguanine, and those are virtually</p> <p>18 the identical adducts that we see when NDMA</p> <p>19 is given to animals.</p> <p>20 And then, in the early 1980s, 11:01 AM</p> <p>21 Autrop Harris and a couple of their</p> <p>22 colleagues, did a series of about seven</p> <p>23 publications where they took five or six</p> <p>24 different human -- this is from humans --</p> <p>25 tissue, and they subjected the human tissue 11:01 AM</p>	<p style="text-align: right;">Page 96</p> <p>1 Q. Okay.</p> <p>2 A. -- and then I came to the Beth</p> <p>3 Israel Deaconess in 2014.</p> <p>4 Q. Okay. And if I understand from</p> <p>5 your CV, under faculty academic appointments, 11:03 AM</p> <p>6 from 2003 to 2013, you were an instructor in</p> <p>7 the Department of Surgery?</p> <p>8 A. Correct.</p> <p>9 Q. And Harvard Medical School doesn't</p> <p>10 have a Department of Surgery. This is, 11:03 AM</p> <p>11 again, the hospital, right?</p> <p>12 A. So I would say Boston Children's</p> <p>13 Hospital.</p> <p>14 Q. Okay. Thank you.</p> <p>15 And you, again, had -- strike 11:03 AM</p> <p>16 that.</p> <p>17 The instructor is the entry-level</p> <p>18 rank in the academic progression to</p> <p>19 professor.</p> <p>20 Do you understand that question? 11:03 AM</p> <p>21 A. In general. However, I would say</p> <p>22 instructor at Harvard Medical School is</p> <p>23 widely considered to be like an assistant</p> <p>24 professor or even higher at many other</p> <p>25 universities. Harvard Medical School is kind 11:04 AM</p>
<p style="text-align: right;">Page 95</p> <p>1 to NDMA.</p> <p>2 This was human lung, bronchus,</p> <p>3 human esophagus, human colon, human pancreas,</p> <p>4 human bladder, and subjected those cells to</p> <p>5 NDMA and saw there was an increase in these 11:02 AM</p> <p>6 DNA adducts. And they could tell by the</p> <p>7 release of carbon dioxide, aldehydes, and</p> <p>8 these DNA adducts that the NDMA had</p> <p>9 metabolized very quickly to the</p> <p>10 cancer-causing metabolites from these human 11:02 AM</p> <p>11 cells that we -- that scientists had seen in</p> <p>12 animals.</p> <p>13 So that's -- those are just a</p> <p>14 couple studies I had cited that -- of</p> <p>15 evidence that NDMA is a human carcinogen, 11:02 AM</p> <p>16 because of the mechanism of action of the</p> <p>17 metabolism of NDMA is virtually identical in</p> <p>18 humans and in animals.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. Doctor, when did you leave 11:02 AM</p> <p>21 Dr. Faulkner's lab?</p> <p>22 I'm trying to tell from your CV.</p> <p>23 A. He passed away in 2008, and then,</p> <p>24 I joined -- I was still at Children's</p> <p>25 Hospital until 2013. I was an instructor -- 11:03 AM</p>	<p style="text-align: right;">Page 97</p> <p>1 of a unique place.</p> <p>2 Q. Let's stick with Harvard.</p> <p>3 Doctor, the instructor is the</p> <p>4 lowest rank in the professor academic ranks,</p> <p>5 isn't it? 11:04 AM</p> <p>6 MR. NIGH: Form objection.</p> <p>7 A. Correct.</p> <p>8 BY MR. FOWLER:</p> <p>9 Q. Okay.</p> <p>10 A. It goes from research fellow to 11:04 AM</p> <p>11 instructor.</p> <p>12 Q. Research fellow is not a faculty</p> <p>13 appointment, is it?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. Correct. 11:04 AM</p> <p>16 BY MR. FOWLER:</p> <p>17 Q. Okay. The lowest rank in the</p> <p>18 faculty academic rankings on the way to</p> <p>19 professor is instructor?</p> <p>20 A. Correct. 11:04 AM</p> <p>21 Q. Okay. Thank you.</p> <p>22 And the next rank is assistant?</p> <p>23 Yes?</p> <p>24 A. Correct.</p> <p>25 Q. And the next rank is associate 11:04 AM</p>

<p style="text-align: right;">Page 98</p> <p>1 professor?</p> <p>2 A. Correct.</p> <p>3 Q. And then the next rank is a</p> <p>4 full-tenured professor, correct?</p> <p>5 A. Correct. 11:04 AM</p> <p>6 Q. And that was always your goal, to</p> <p>7 become a full-tenured professor, isn't it,</p> <p>8 sir?</p> <p>9 MR. NIGH: Hold on. Form</p> <p>10 objection. 11:05 AM</p> <p>11 A. My goal has been on cancer and</p> <p>12 mechanisms of cancer and trying to find a</p> <p>13 cure to cancer. My goal has not been on</p> <p>14 career promotion. I am in the process of</p> <p>15 going to the associate professor, but I 11:05 AM</p> <p>16 haven't focused on career promotion.</p> <p>17 If I had wanted to do that, I</p> <p>18 could have left Harvard Medical School and</p> <p>19 gone to many universities and focused on</p> <p>20 career promotion. 11:05 AM</p> <p>21 BY MR. FOWLER:</p> <p>22 Q. Doctor, you were not advanced</p> <p>23 in 10 years as an instructor in the</p> <p>24 Department of Surgery, correct?</p> <p>25 MR. NIGH: Form objection. 11:05 AM</p>	<p style="text-align: right;">Page 100</p> <p>1 on cancer mechanisms and our trying to find</p> <p>2 cures for cancer rather than career</p> <p>3 promotion.</p> <p>4 If I had wanted to do career</p> <p>5 promotion, I was offered full -- 11:07 AM</p> <p>6 tenured-offered positions at Vanderbilt, UC</p> <p>7 Davis, University of Michigan, places that I</p> <p>8 could have focused on career promotion.</p> <p>9 Part of it was also the department</p> <p>10 I was in was with Dr. Folkman, and I had some 11:07 AM</p> <p>11 really close colleagues, such as Mark Kieran,</p> <p>12 who I enjoyed collaborating with.</p> <p>13 And part of the issue also was my</p> <p>14 wife as a pediatrician, and her family's in</p> <p>15 the Massachusetts area. So I didn't -- we 11:07 AM</p> <p>16 didn't want to move as a family.</p> <p>17 So if I had focused on career</p> <p>18 promotion, I would have accepted</p> <p>19 faculty-tenured positions at Vanderbilt and</p> <p>20 other places that I was offered. 11:07 AM</p> <p>21 BY MR. FOWLER:</p> <p>22 Q. So you weren't interested in</p> <p>23 promotion where you were at Harvard; is that</p> <p>24 right?</p> <p>25 MR. NIGH: Form objection. 11:07 AM</p>
<p style="text-align: right;">Page 99</p> <p>1 A. I'm not sure what you mean by</p> <p>2 "advanced."</p> <p>3 BY MR. FOWLER:</p> <p>4 Q. You were -- you were never</p> <p>5 promoted to the next level, to assistant 11:05 AM</p> <p>6 professor, in the Department of Surgery, in</p> <p>7 the 10 years that you were there as an</p> <p>8 instructor, correct?</p> <p>9 A. Yeah, that is correct. But there</p> <p>10 are circumstances where tenures as an 11:05 AM</p> <p>11 instructor at Harvard Medical School is -- I</p> <p>12 had two R01 grants that most professors don't</p> <p>13 have. And part of the reason for the career</p> <p>14 part was when Dr. Folkman passed away, sadly,</p> <p>15 in 2008, part of the process is you -- it was 11:06 AM</p> <p>16 a lot of flux, and so I ended up moving to</p> <p>17 the Beth Israel Deaconess Medical Center.</p> <p>18 Q. You left the Department of Surgery</p> <p>19 having never advanced beyond instructor,</p> <p>20 correct? 11:06 AM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A. As instructor, yes, that's</p> <p>23 correct. But I would say that instructor at</p> <p>24 Harvard Medical School is a very prestigious</p> <p>25 position, and, as I said, I was focused more 11:06 AM</p>	<p style="text-align: right;">Page 101</p> <p>1 A. So as I mentioned, because my</p> <p>2 mentor Dr. Judah Folkman passed away suddenly</p> <p>3 in 2008, then, the department was in a state</p> <p>4 of flux. So I wasn't -- yeah, that's</p> <p>5 correct. I was not focused on career 11:08 AM</p> <p>6 promotion during that time.</p> <p>7 MR. FOWLER: Let me mark the next</p> <p>8 exhibit, please. Is that 4?</p> <p>9 THE REPORTER: Can we take a</p> <p>10 break? 11:08 AM</p> <p>11 MR. FOWLER: We can -- let's</p> <p>12 take 10 minutes for the court reporter's</p> <p>13 comfort.</p> <p>14 THE VIDEOGRAPHER: The time is</p> <p>15 11:07. We're off the record. 11:08 AM</p> <p>16 (Recess taken at 11:16 a.m. to 11:22 a.m.)</p> <p>17 THE VIDEOGRAPHER: The time is</p> <p>18 11:22. We're back on the record.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. Doctor, while you were an 11:23 AM</p> <p>21 instructor in the Department of Surgery for</p> <p>22 10 years, that was at the Beth Israel</p> <p>23 Deaconess Medical Center, correct?</p> <p>24 A. Oh, no. Actually, the 10 years</p> <p>25 was at Boston Children's Hospital from -- 11:23 AM</p>

<p style="text-align: right;">Page 102</p> <p>1 Boston Children's Hospital.</p> <p>2 Q. Where you have faculty</p> <p>3 appointment, 2003 to 2013, surgery, Harvard</p> <p>4 Medical School, Boston. Which hospital were</p> <p>5 you in the Department of Surgery for? 11:23 AM</p> <p>6 A. Boston Children's Hospital. Right</p> <p>7 above it --</p> <p>8 Q. I -- yes, I'm with you, sir.</p> <p>9 A. Oh, it might be more clear on this</p> <p>10 next page. 11:24 AM</p> <p>11 MR. FOWLER: We're not going to</p> <p>12 mark those, so.</p> <p>13 (Exhibit 5, removed.)</p> <p>14 (Exhibit 6, removed.)</p> <p>15 BY MR. FOWLER: 11:24 AM</p> <p>16 Q. Doctor, when you left that</p> <p>17 position, it's been your testimony that you</p> <p>18 were recruited over to the Department of</p> <p>19 Pathology.</p> <p>20 Was that a fair statement? 11:24 AM</p> <p>21 A. At Beth Israel Deaconess Medical</p> <p>22 Center?</p> <p>23 Q. Yes, sir.</p> <p>24 A. Yes.</p> <p>25 Q. Okay. And as part of that deal, 11:24 AM</p>	<p style="text-align: right;">Page 104</p> <p>1 (Exhibit 5, In Re: Actos (Pioglitazone)</p> <p>2 Products Liability Litigation (MDL 2299),</p> <p>3 marked for identification.)</p> <p>4 BY MR. FOWLER:</p> <p>5 Q. Before you, Doctor, Exhibit 5, 11:26 AM</p> <p>6 that's your name on the -- on the front cover</p> <p>7 there, the Beth Israel Deaconess, sir?</p> <p>8 A. Yes.</p> <p>9 Q. And you recognize this as your</p> <p>10 report that you submitted in the Actos 11:26 AM</p> <p>11 litigation?</p> <p>12 A. Correct.</p> <p>13 Q. And directing your attention to</p> <p>14 page 2, at the bottom of the last full</p> <p>15 paragraph, quote, "I am on a tenure track for 11:26 AM</p> <p>16 an accelerated promotion to associate</p> <p>17 professor at Harvard Medical School and then</p> <p>18 to professor of pathology at Harvard Medical</p> <p>19 School."</p> <p>20 Do you see that? 11:26 AM</p> <p>21 A. Correct.</p> <p>22 Q. And when you wrote that, you</p> <p>23 believed that to be true?</p> <p>24 A. So -- yes. Tenure at Harvard</p> <p>25 Medical School is not -- there's no 11:27 AM</p>
<p style="text-align: right;">Page 103</p> <p>1 if you will, you were promised an accelerated</p> <p>2 promotion program to professor, correct?</p> <p>3 A. Well, nothing is in writing at</p> <p>4 Harvard Medical School. The process of</p> <p>5 promotion -- there's a certain process it 11:24 AM</p> <p>6 goes. So I was -- there's no -- there's no</p> <p>7 tenure at Harvard Medical School, so the goal</p> <p>8 of everyone is to go to associate professor</p> <p>9 and full professor, but there's no promise</p> <p>10 like that. 11:25 AM</p> <p>11 Q. Is it true or is it not true that</p> <p>12 you have held yourself out as being brought</p> <p>13 over to that program into an accelerated --</p> <p>14 into an accelerated-promotion program to</p> <p>15 associate professor and then full professor? 11:25 AM</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A. So when I was hired, everyone's</p> <p>18 goal is to get promoted as soon as possible,</p> <p>19 but there's certain criteria you have to</p> <p>20 meet. And then -- so, like I said, I'm in 11:25 AM</p> <p>21 the process now of going to associate</p> <p>22 professor.</p> <p>23 MR. FOWLER: Let me mark</p> <p>24 Exhibit 5, please. And I'm sorry, madam</p> <p>25 court reporter. 11:26 AM</p>	<p style="text-align: right;">Page 105</p> <p>1 guaranteed tenure unless you have a chair, so</p> <p>2 it's a little complicated.</p> <p>3 Q. Sure. But can we agree that you</p> <p>4 considered yourself to be on an</p> <p>5 accelerated -- your words, accelerated 11:27 AM</p> <p>6 promotion to associate professor?</p> <p>7 A. Correct.</p> <p>8 Q. And you wrote this report in 2013?</p> <p>9 A. Correct.</p> <p>10 Q. And we're eight years later. And 11:27 AM</p> <p>11 you're not associate professor?</p> <p>12 A. Like I said before, the last</p> <p>13 couple years, I've been more focused on our</p> <p>14 lab science and the cancer discoveries than</p> <p>15 my career promotion. I'm in the process of 11:27 AM</p> <p>16 going to associate professor. That hasn't</p> <p>17 been the highest priority for me now.</p> <p>18 Q. Doctor, what do you think you</p> <p>19 meant -- let me start that again.</p> <p>20 You used the word accelerated 11:27 AM</p> <p>21 program to associate professor. Those are</p> <p>22 your words, right? Sir?</p> <p>23 A. Correct.</p> <p>24 Q. And on your current report, in</p> <p>25 this case, you make no mention of being on 11:28 AM</p>

<p style="text-align: right;">Page 106</p> <p>1 any sort of tenure track or any sort of track 2 at all to professor, right? 3 A. Correct. 4 Q. And do you consider the eight 5 years that you remained as assistant 11:28 AM 6 professor and not associate professor -- do 7 you think that's been accelerated? 8 MR. NIGH: Form objection. 9 A. So the -- so the last six, seven, 10 years that I've been assistant professor at 11:28 AM 11 Beth Israel Deaconess Medical Center, we have 12 had a very productive time. We've had five 13 or six high-impact publications over the last 14 three years, and I'm in the process of 15 getting promoted to associate professor. It 11:28 AM 16 wasn't the highest priority for me currently. 17 BY MR. FOWLER: 18 Q. Let's talk about that process. 19 In order to be advanced, your 20 department has to put you up for that 11:29 AM 21 promotion, correct? 22 A. Correct. 23 Q. Have you been put up for that 24 promotion? 25 MR. NIGH: Form objection. 11:29 AM</p>	<p style="text-align: right;">Page 108</p> <p>1 BY MR. FOWLER: 2 Q. Has your department put you up for 3 associate professor? 4 A. No. 5 Q. So your department hasn't yet 11:30 AM 6 voted -- there's a vote, right, to get to 7 that next stage? 8 A. No, there -- no vote. My chair 9 has told me when I feel that the paperwork is 10 ready, I'll go up for associate professor. I 11:30 AM 11 have -- I had two R01s before, as an 12 instructor, where many professors don't have 13 those two R01s, but that NIH funding ended. 14 I'm in the process of obtaining 15 new R01, so I wanted to obtain a new R01 11:30 AM 16 before we start the paperwork. My chair is 17 very supportive to start the paperwork once I 18 get one of these R01s. 19 So that's what I want to -- the 20 funding for these R01s is very competitive, 11:30 AM 21 as you -- as you may know, and I'm in the 22 process of resubmitting a couple NIH grants. 23 Q. Doctor, your R01s ended in 2015 24 and the other in 2016, correct? 25 A. Correct. 11:31 AM</p>
<p style="text-align: right;">Page 107</p> <p>1 A. Currently, I'm in -- so currently, 2 what my -- I had two NIH fundings that ended, 3 the R01, and part of that criteria to go to 4 associate, I have enough publications. I 5 have -- and my chair has said, basically -- 11:29 AM 6 ideally, we want to get one more R01 NIH 7 grant before we do the paperwork for the 8 associate professor, so... 9 BY MR. FOWLER: 10 Q. So when you just testified a 11:29 AM 11 minute ago that that was in process, you 12 haven't taken the first step, which is your 13 department putting you forward. That's 14 step 1, and you haven't done that, right? 15 That hasn't been done for you? 11:29 AM 16 MR. NIGH: Form objection. 17 MR. FOWLER: These are going to be 18 short questions for yes or no. 19 MR. NIGH: Form -- form objection. 20 He does not have to answer yes or no if 11:29 AM 21 the question doesn't call for a yes or 22 no. 23 MR. FOWLER: Fair enough, Counsel. 24 I'll be careful to phrase it. 25 / 11:30 AM</p>	<p style="text-align: right;">Page 109</p> <p>1 Q. And NIH grants like that can be 2 renewed, right? 3 A. Certain ones can -- 4 Q. That's right. 5 A. -- my second R01 was an RFA, which 11:31 AM 6 cannot be renewed. It's a one-time one -- 7 THE REPORTER: I'm sorry, my 8 second ROI was? 9 THE WITNESS: R01, it's called 10 an RFA, and those cannot be renewed. 11:31 AM 11 BY MR. FOWLER: 12 Q. Okay. The 2015 one that expired, 13 you could have applied for a renewal. Did 14 you? 15 A. We -- I thought about it, and we 11:31 AM 16 had enough publications to do it, but we had 17 shift gears and were working on a different 18 topic. So at the time, I didn't even try to 19 renew it. 20 Q. And grant renewals are something 11:31 AM 21 that's peer-reviewed, right? 22 A. Correct. 23 Q. So if you had submitted something 24 for a renewal, others would have looked at 25 your work and determined whether you'd made 11:31 AM</p>

<p style="text-align: right;">Page 110</p> <p>1 any progress or not in determining if you get 2 your renewal. 3 That's how it works, right? 4 A. Correct. We did not submit that 5 first R01 for a renewal because we switched. 11:32 AM 6 Working from that R01 was on the role of 7 epoxyeicosatrienoic acids in cancer 8 metastasis, and we switched to working with 9 other lipid mediators. 10 And we were focused -- like I 11:32 AM 11 said, two -- one drug we put in the clinic 12 for cancer patients, and another drug we put 13 into the clinic for -- were in the process -- 14 called resolvents, that were in the process 15 of putting into cancer patients. 11:32 AM 16 So I was focused more on those 17 goals rather than career promotion and 18 getting the R01s that I wanted to get for the 19 career promotion. 20 So my goal also has been -- with 11:32 AM 21 COVID, everything got delayed, and a lot of 22 paperworks also were delayed, so. 23 Q. Paperwork? 24 A. For some of the grants that we 25 were going to submit. All the experiments 11:32 AM</p>	<p style="text-align: right;">Page 112</p> <p>1 opposed to Dr. Henderson's lab as, the R01. 2 A. This is an SBIR. 3 Q. It's an R01 grant. Is it or not? 4 A. Actually, I don't think it's an 5 R01. It's a -- 11:34 AM 6 Q. Fair enough. It's an NIH -- 7 A. It's an NIH grant. 8 Q. And does any of the money from 9 that NIH grant go into your lab as opposed to 10 Dr. Henderson's? 11:34 AM 11 A. We get some of the money. 12 Q. What work are you actually doing 13 under that grant? 14 A. So that's a bladder cancer grant, 15 and we made the discovery in 2019 that a dual 11:34 AM 16 COX-2/sEH inhibitor, which basically blocks 17 two lipid pathways and it blocks inflammation 18 and stimulates the clearing of inflammation 19 that we call the resolution inflammation -- 20 we had shown that in ovarian cancer in a 2019 11:34 AM 21 PNAS publication. 22 And that grant is using that drug, 23 this dual COX-2/sEH inhibitor, in bladder 24 cancer. So the goal is to get this drug in 25 the clinic to treat bladder cancer patients. 11:34 AM</p>
<p style="text-align: right;">Page 111</p> <p>1 got pushed off and delayed, so. 2 Q. But that was only in 2019 that 3 that could have possibly happened, correct? 4 A. Correct. 5 Q. Okay. The only R01 grant that you 11:33 AM 6 have listed on your CV right now has a 7 Dr. Henderson as the PI, correct? 8 A. Correct. 9 Q. And you list yourself as a -- 10 A. I'm the consortium PI. 11:33 AM 11 Q. What does that mean? 12 A. So it -- this is called an SBIR 13 grant so -- 14 (Reporter clarification.) 15 THE WITNESS: SBIR, SBIR. 11:33 AM 16 A. And that -- it works -- these are 17 the grants with -- work with industry to try 18 to translate -- actually, this is a drug that 19 we're trying to put in cancer patients, and 20 we're responsible for some of the experiments 11:33 AM 21 on that grant. 22 BY MR. FOWLER: 23 Q. Well, that's what I was going to 24 ask. Because I wanted to know if any money 25 for that grant is going to your lab as 11:33 AM</p>	<p style="text-align: right;">Page 113</p> <p>1 MR. NIGH: And Mr. Fowler, I don't 2 know if you've moved on from this 3 document, the Actos bladder cancer 4 expert report? 5 MR. FOWLER: I'm way passed 11:35 AM 6 that. 7 MR. NIGH: Well, we can't tell 8 if -- well, we haven't gone to another 9 document. That's why I can't tell. But 10 we can't tell if this is under seal or 11:35 AM 11 not, or any of the issues here under 12 seal, so we just need to note that for 13 the record. 14 MR. FOWLER: Right. Well, it is 15 filed. You can see the "filed" right 11:35 AM 16 across the top. 17 MR. NIGH: I see "filed." I just 18 can't tell under seal. 19 MR. FOWLER: And there's time to 20 deem things confidential, and 11:35 AM 21 absolutely, I asked the same question. 22 MR. NIGH: Okay. 23 MR. FOWLER: So, you know, 24 provisional confidentiality, whatever 25 you'd like. 11:35 AM</p>

<p style="text-align: right;">Page 114</p> <p>1 MR. NIGH: Sure. Go ahead. Sure.</p> <p>2 BY MR. FOWLER:</p> <p>3 Q. Doctor, do you think you can be</p> <p>4 advanced to full professor at Harvard Medical</p> <p>5 School without being a principal investigator 11:35 AM</p> <p>6 on an R01 grant?</p> <p>7 A. Yeah, I was a PI on two R01 grants</p> <p>8 and -- getting -- going to pathology</p> <p>9 professor at Harvard is not just having a</p> <p>10 one -- a single R01 PI grant. There's 11:35 AM</p> <p>11 more -- it's becoming expertise in the field.</p> <p>12 I have -- my lab has five</p> <p>13 high-impact publications in the last three</p> <p>14 years. We've had a 28JX med paper. We've</p> <p>15 had three PNAS papers. We've made important 11:36 AM</p> <p>16 discoveries that were translating to the</p> <p>17 clinic.</p> <p>18 Part of going to a professor at</p> <p>19 Harvard is you also want to have some NIH</p> <p>20 funding, so that's what -- I'm applying for 11:36 AM</p> <p>21 those grants now.</p> <p>22 Q. My question was simply this,</p> <p>23 Doctor -- let me ask.</p> <p>24 Are you aware of any full</p> <p>25 professor in the Department of Pathology at 11:36 AM</p>	<p style="text-align: right;">Page 116</p> <p>1 A. -- you know.</p> <p>2 Q. Your publications and</p> <p>3 presentations have tailed off in the last</p> <p>4 number of years, haven't they?</p> <p>5 A. We've had five -- 11:37 AM</p> <p>6 MR. NIGH: Form objection.</p> <p>7 A. -- publications in the last three</p> <p>8 years.</p> <p>9 BY MR. FOWLER:</p> <p>10 Q. I'm asking about yours, sir. 11:37 AM</p> <p>11 Your -- where you are a named</p> <p>12 author, the number of publications, since</p> <p>13 2015 or 2017, have been less than you have</p> <p>14 previously published each year prior to that?</p> <p>15 MR. NIGH: Form objection. 11:37 AM</p> <p>16 A. So we focus on high-impact papers,</p> <p>17 and the last three years -- these are</p> <p>18 high-impact journals -- we've had, 2019, two</p> <p>19 PNAS publications; 28, a JX Med publication;</p> <p>20 2019, a Journal of Clinical Investigation 11:38 AM</p> <p>21 papers, and these high-impact papers take</p> <p>22 three to four years of research. So they --</p> <p>23 there's a lot of -- the bar to get published</p> <p>24 in a high-impact journal has gone up.</p> <p>25 So depending on the project -- our 11:38 AM</p>
<p style="text-align: right;">Page 115</p> <p>1 Harvard Medical School who does not have an</p> <p>2 R01 grant?</p> <p>3 A. Yes.</p> <p>4 Q. Has anybody ever been promoted to</p> <p>5 full professor without being a PI on an R01 11:36 AM</p> <p>6 grant?</p> <p>7 A. Yes.</p> <p>8 Q. Okay.</p> <p>9 Who?</p> <p>10 A. So my -- I have close colleagues 11:36 AM</p> <p>11 who are currently professors in our</p> <p>12 department who don't have an R01 and are</p> <p>13 pathology professors.</p> <p>14 Q. Do you know if they had an R01 at</p> <p>15 the time they were advanced? 11:37 AM</p> <p>16 A. I would have to look specifically,</p> <p>17 but the criteria of getting advanced to a</p> <p>18 professor is more than just having -- for me</p> <p>19 to get a third R01 grant. A lot of it also</p> <p>20 is the amount of funding you bring in. So I 11:37 AM</p> <p>21 bring in equivalent funding in other ways.</p> <p>22 You know, some of it's the peer-reviewed</p> <p>23 publications; some of it's teaching; some of</p> <p>24 it's having expertise in a field --</p> <p>25 Q. Right. 11:37 AM</p>	<p style="text-align: right;">Page 117</p> <p>1 JCI paper in 2019, the experiments started in</p> <p>2 2015. Our JEM paper in 2018 probably started</p> <p>3 in 2011. So some of these papers take five,</p> <p>4 six, seven years to complete the project.</p> <p>5 BY MR. FOWLER: 11:38 AM</p> <p>6 Q. Sir, have you ever been nominated</p> <p>7 to the American Society for Clinical</p> <p>8 Investigation, ASCI?</p> <p>9 A. No.</p> <p>10 Q. That's one of the core honorary 11:39 AM</p> <p>11 societies in the field that you work in,</p> <p>12 isn't it?</p> <p>13 A. Right. And I --</p> <p>14 Q. A field -- a field that you've</p> <p>15 worked in for the last 15 years or more, 11:39 AM</p> <p>16 right?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 A. No, the field I work in is a</p> <p>19 bioactive lipid field; and in 2015, at the</p> <p>20 bioactive lipid meeting, I won the young -- 11:39 AM</p> <p>21 early-career young investigator award, which</p> <p>22 meets every two years, and it's the most</p> <p>23 prestigious bioactive lipid meeting.</p> <p>24 The one that you mentioned is more</p> <p>25 for clinical investigators. I'm a basic 11:39 AM</p>

<p style="text-align: right;">Page 118</p> <p>1 scientist. And, also, I do pathology 2 research. And in 2015 I won the Ramzi Cotran 3 career investigator award, which is one of 4 the most prestigious young investigator 5 awards you can get in the field of pathology, 11:39 AM 6 named after probably -- every medical student 7 does Ramzi Cotran and Kumar, the textbook of 8 pathology, second year of med school, and 9 when Ramzi Cotran passed away, the ASIP, 10 American Society of Investigative Pathology, 11:40 AM 11 started this Razi Cotran early-career 12 investigator award, which I won in 2015. 13 So the two fields that I've -- 14 that I work in, I've won early-career 15 investigator awards. So the 2015 bioactive 11:40 AM 16 lipid one, which was in Budapest in Hungary, 17 and then in 2015 the ASIP Ramzi Cotran 18 early-career investigator award. 19 BY MR. FOWLER: 20 Q. Doctor, you're not an 11:40 AM 21 toxicologist, correct? 22 MR. NIGH: Form objection. 23 A. Just so I understand, are you 24 talking about board-certified toxic -- 25 / 11:40 AM</p>	<p style="text-align: right;">Page 120</p> <p>1 BY MR. FOWLER: 2 Q. On drugs, right, sir? 3 A. Yeah, does a drug induce weight 4 loss in an animal, like over 15 percent 5 weight loss. 11:41 AM 6 Q. Fair enough. Fair enough, sir. 7 But none of your research has ever 8 been taking a chemical that's not a drug and 9 evaluating it from a toxicity perspective and 10 making determinations from that? 11:41 AM 11 You've never done that; isn't that 12 true? 13 MR. NIGH: Form objection. 14 A. Well, currently, we're translating 15 another drug -- well, correct -- 11:42 AM 16 Q. Okay. 17 A. -- I don't personally -- what we 18 do is we set up tox studies, but we send them 19 out to somebody. 20 BY MR. FOWLER: 11:42 AM 21 Q. Okay. Fair enough. 22 And you've never, in your career 23 prior to this litigation, studied NDMA as 24 a -- let me just leave it at that. You've 25 never studied NDMA, have you? 11:42 AM</p>
<p style="text-align: right;">Page 119</p> <p>1 BY MR. FOWLER: 2 Q. You're not a -- well, let's start 3 there. 4 You're not a board-certified 5 toxicologist? 11:40 AM 6 A. Correct. 7 Q. You're not trained in toxicology? 8 MR. NIGH: Form -- form 9 objection. 10 A. While I'm not formally trained in 11:41 AM 11 toxicology, it is something that we use in 12 our everyday animal experiments and when 13 we're translating drugs to the clinic. 14 BY MR. FOWLER: 15 Q. You're not qualified, are you, to 11:41 AM 16 render opinions about the toxicity of a 17 chemical, sir, are you? 18 MR. NIGH: Form objection. 19 A. We do that every day in the lab. 20 One of the animal experiments we do is does a 11:41 AM 21 drug -- is it toxic to mice. Is there 22 greater than 15 percent body weight. These 23 are -- these are experiments I've been doing 24 for the last 30 years. 25 / 11:41 AM</p>	<p style="text-align: right;">Page 121</p> <p>1 MR. NIGH: Form objection. 2 A. Actually, we use NDMA and NDEA in 3 the lab to initiate cancer and to induce 4 inflammation and oxidative stress in the lab. 5 BY MR. FOWLER: 11:42 AM 6 Q. Yes, sir. But you don't study the 7 effects of NDMA, other than using it as a 8 tumor inducer so you can study other things 9 against those tumors, right? 10 MR. NIGH: Form objection. 11:42 AM 11 A. Correct, we use it in the lab to 12 initiate cancer and to study the key 13 characteristics of mechanisms of cancer. 14 BY MR. FOWLER: 15 Q. Okay. And you're not a 11:43 AM 16 pharmacologist, right? 17 MR. NIGH: Form objection. 18 BY MR. FOWLER: 19 Q. By either board certification or 20 training or background, you're not a 11:43 AM 21 pharmacology person, right? 22 MR. NIGH: Form objection. 23 A. Correct -- 24 BY MR. FOWLER: 25 Q. Okay. 11:43 AM</p>

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1 A. -- however, we use pharmacology in
2 our everyday research.
3 BY MR. FOWLER:
4 Q. And you're not a pharmacokinetics
5 expert. You wouldn't hold yourself out as a 11:43 AM
6 pharmacokinetics expert, would you?
7 MR. NIGH: Form objection.
8 A. Well, we do --
9 BY MR. FOWLER:
10 Q. I'm sorry, who's the "we" so I can 11:43 AM
11 understand that, please --
12 A. Oh, okay. I can say "me." When I
13 say "we," it's our laboratory, but I lead the
14 laboratory --
15 Q. I'm much more interested in what 11:43 AM
16 you do, sir.
17 A. Yeah. Okay.
18 Q. Yeah. Okay. I just -- didn't
19 want to be confused. My apologies. Please
20 continue. 11:43 AM
21 A. What was the question?
22 Q. That you're not an expert in
23 pharmacokinetics?
24 A. Well, we use pharmacokinetics in
25 a -- like I mentioned, what we're doing now 11:43 AM

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1 is translating a drug called a resolvent to
2 the clinic. We're working with industry --
3 (Reporter clarification.)
4 THE WITNESS: Is to translate a
5 drug called resolvers into the clinic. 11:44 AM
6 And we do -- we set up
7 pharmacokinetic studies. So we'll set
8 up -- we call them PK studies,
9 pharmacokinetic studies, and then we
10 send the blood and the plasma to 11:44 AM
11 somebody else who runs the actual
12 studies, and then we all will meet to
13 analyze the data.
14 BY MR. FOWLER:
15 Q. Yes, sir. And let me get a handle 11:44 AM
16 on the "we."
17 How many Ph.D.s are in the lab
18 that you work in?
19 A. So currently?
20 Q. I'll take that. 11:44 AM
21 A. Yeah. So right now, I have a
22 postdoctoral fellow, who's a Ph.D. She is in
23 her second -- doing her second postdoc. And
24 I have two research assistants, who are not a
25 Ph.D., and then one medical -- one student. 11:44 AM

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1 Q. So that -- you've just listed a
2 total of five people, right?
3 A. So one -- I think your question
4 was how many Ph.D.s?
5 Q. That was my question, but maybe I 11:45 AM
6 should have started with, how many people
7 work in the lab that you work in?
8 A. I just answered.
9 Q. Five?
10 A. Yes, we have a postdoctoral fellow 11:45 AM
11 and two research assistants and a student and
12 me.
13 Q. And this -- and this lab, does it
14 have a name?
15 A. It's Panigrahy Laboratory. 11:45 AM
16 (Reporter clarification.)
17 THE WITNESS: It's Panigrahy
18 Laboratory.
19 BY MR. FOWLER:
20 Q. Oh, it's your named lab. Okay. I 11:45 AM
21 understand how that works.
22 A. We don't really --
23 Q. Well, is that the formal name?
24 Because -- you've heard of, like, the McGowan
25 laboratory out of the University of 11:45 AM

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1 Pittsburgh and things like that, where
2 there's a name for the lab?
3 A. Right.
4 Q. If John Q. Public was looking at
5 your laboratory, what name would come up? 11:45 AM
6 A. Yeah, they would say the Panigrahy
7 laboratory.
8 Q. Okay. Fair enough. And that's
9 within the Department of Pathology?
10 A. Yes. 11:45 AM
11 Q. Okay. And how long has -- and do
12 you report -- who do you report to?
13 A. I have a chairman.
14 Q. Of the Department of Pathology?
15 A. Of pathology, yeah. 11:46 AM
16 Q. And how many other such,
17 quote/unquote, "labs" are there within that
18 department?
19 A. Oh, there's at least five or six,
20 something like that. 11:46 AM
21 Q. And each has its own sort of
22 niche?
23 A. Yeah, everyone has an expertise
24 that they work on and...
25 Q. Okay. And within your laboratory, 11:46 AM

<p style="text-align: right;">Page 126</p> <p>1 are you able to -- in a sentence, maybe</p> <p>2 two -- tell me what the niche is for your</p> <p>3 lab, the specialty?</p> <p>4 A. Yeah, sure. We worked on lipids</p> <p>5 that stimulate the resolution of 11:46 AM</p> <p>6 inflammation.</p> <p>7 Q. Perfect.</p> <p>8 (Reporter clarification.)</p> <p>9 THE WITNESS: Inflammation.</p> <p>10 BY MR. FOWLER: 11:46 AM</p> <p>11 Q. And, Doctor, you would agree that</p> <p>12 you're not trained or qualified to offer</p> <p>13 opinions about how nitrosamines are</p> <p>14 metabolized in the body, in the human body?</p> <p>15 MR. NIGH: Form objection. 11:46 AM</p> <p>16 A. I'm not sure if I understand the</p> <p>17 question. We study metabolism of other</p> <p>18 chemicals. You know, like I mentioned, we're</p> <p>19 translating drugs to the clinic for cancer</p> <p>20 drugs. So we do PK studies and -- you know, 11:47 AM</p> <p>21 so I have to know about metabolism and be</p> <p>22 familiar with it and, yeah, I use it as part</p> <p>23 of the research that we do.</p> <p>24 BY MR. FOWLER:</p> <p>25 Q. Okay. Would you agree, sir, 11:47 AM</p>	<p style="text-align: right;">Page 128</p> <p>1 you had questions about what a slide meant,</p> <p>2 for example.</p> <p>3 A. Well, I would only go -- yeah,</p> <p>4 first we look at the slides ourselves and</p> <p>5 then meet with a pathologist, who's -- 11:48 AM</p> <p>6 usually, the ones I work with are at</p> <p>7 Children's Hospital or Beth Israel. And</p> <p>8 then, we would just walk over with the slides</p> <p>9 and review the slides with them.</p> <p>10 Q. Doctor, if you were to go through 11:48 AM</p> <p>11 your CV -- which, of course, we have done --</p> <p>12 do you agree with me that you don't have any</p> <p>13 publications that talk about a risk</p> <p>14 assessment, a cancer risk assessment, in</p> <p>15 humans? You've never published on that 11:48 AM</p> <p>16 before; isn't that true?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 A. Correct.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. You've never, prior to this case, 11:49 AM</p> <p>21 expressed in your professional life any</p> <p>22 opinions or publications or anything that</p> <p>23 arrived at a determination of an increased</p> <p>24 risk in humans -- increased risk of cancer?</p> <p>25 MR. NIGH: Form -- 11:49 AM</p>
<p style="text-align: right;">Page 127</p> <p>1 you're not a statistician?</p> <p>2 MR. NIGH: Form objection.</p> <p>3 A. Well, every medical student</p> <p>4 usually gets some statistics in medical</p> <p>5 school. And baseline statistics, scientists 11:47 AM</p> <p>6 use, like, for example, p-values, ANOVA.</p> <p>7 But I think, your question, if you</p> <p>8 go to more complex statistical modeling, we</p> <p>9 have a board-certified statistician that we</p> <p>10 run things by. 11:47 AM</p> <p>11 BY MR. FOWLER:</p> <p>12 Q. Outside your lab?</p> <p>13 A. Yeah, we collaborate with --</p> <p>14 Q. And the same sort of deal like</p> <p>15 where you send blood outside your lab? 11:47 AM</p> <p>16 A. Yes.</p> <p>17 Q. Do you send slides outside your</p> <p>18 lab too?</p> <p>19 A. Slides?</p> <p>20 Q. Pathology slides. 11:48 AM</p> <p>21 A. No. If I have slides, we'll just</p> <p>22 walk over to the pathology department and</p> <p>23 look under the microscope.</p> <p>24 Q. Right. But you mentioned before</p> <p>25 that you would go to an actual pathologist if 11:48 AM</p>	<p style="text-align: right;">Page 129</p> <p>1 MR. FOWLER: Thank you, Counsel.</p> <p>2 MR. NIGH: Form objection.</p> <p>3 A. Well, when we study, like I said</p> <p>4 before, drugs that inhibit cancer, we modeled</p> <p>5 the human cancer in animals, and we're 11:49 AM</p> <p>6 going -- now the drug that I mentioned, the</p> <p>7 solvents, we're putting it into phase 1</p> <p>8 clinical trials next year and then phase 2.</p> <p>9 So part of what we do every day is</p> <p>10 looking at that in animal models and looking 11:49 AM</p> <p>11 at the context of translating a drug from an</p> <p>12 animal to a person.</p> <p>13 BY MR. FOWLER:</p> <p>14 Q. Doctor, have you ever -- pardon</p> <p>15 me -- have you ever performed a TD 50 linear 11:50 AM</p> <p>16 back extrapolation calculation?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 A. So the TD 50 -- I've done it</p> <p>19 following -- relevant to this case.</p> <p>20 BY MR. FOWLER: 11:50 AM</p> <p>21 Q. Okay. Thank you for that</p> <p>22 clarification.</p> <p>23 Prior to this litigation in your</p> <p>24 professional life, isn't it true that you've</p> <p>25 never done a TD 50 linear back extrapolation 11:50 AM</p>

<p style="text-align: right;">Page 130</p> <p>1 for any potential carcinogen?</p> <p>2 A. Correct.</p> <p>3 Q. And it follows, I would assume,</p> <p>4 that you've also never done a benchmark dose</p> <p>5 level calculation for any particular 11:51 AM</p> <p>6 potential carcinogen?</p> <p>7 A. Correct.</p> <p>8 Q. And you've never done a risk</p> <p>9 assessment that evaluated whether exposure to</p> <p>10 any level of a potential carcinogen was 11:51 AM</p> <p>11 likely to cause cancer in humans?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. Correct.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. Shifting gears, sir, am I correct 11:51 AM</p> <p>16 that when you were a testifying expert for</p> <p>17 plaintiffs in the Actos litigation, one of</p> <p>18 those attorneys was Mr. Adam Slater?</p> <p>19 MR. NIGH: Form objection.</p> <p>20 A. It sounds familiar, but I can't -- 11:51 AM</p> <p>21 BY MR. FOWLER:</p> <p>22 Q. Do you recollect, sitting here</p> <p>23 today, who engaged you? Who hired you for</p> <p>24 the Actos litigation?</p> <p>25 A. Yeah, it was Stephanie -- 11:51 AM</p>	<p style="text-align: right;">Page 132</p> <p>1 Were you told anything about the</p> <p>2 case at the time you were first contacted,</p> <p>3 sir?</p> <p>4 A. No. I was just given -- here are</p> <p>5 the questions and I did my independent 11:53 AM</p> <p>6 peer-review analysis.</p> <p>7 Q. Were you aware that you were</p> <p>8 contacted by attorneys that are representing</p> <p>9 the patients as opposed to representing the</p> <p>10 drug company? Were you aware of that? 11:53 AM</p> <p>11 A. Well, as I did my research --</p> <p>12 Q. I'm sorry. I was a poor question.</p> <p>13 When you were first contacted to</p> <p>14 be an expert in this case, did you understand</p> <p>15 you were being contacted by the plaintiffs. 11:53 AM</p> <p>16 A. Yes.</p> <p>17 Q. Okay. Thank you.</p> <p>18 And I assume in that initial</p> <p>19 conversation you were -- you were told</p> <p>20 something about the issue of NDMA and NDEA 11:53 AM</p> <p>21 exposure, correct, and the question of the</p> <p>22 carcinogenicity? That's what I was --</p> <p>23 A. Yes, I was asked, you know, do</p> <p>24 these cause cancer in humans.</p> <p>25 Q. Yes, sir. Yes, sir. 11:54 AM</p>
<p style="text-align: right;">Page 131</p> <p>1 Stephanie -- I'm blanking her last name.</p> <p>2 Q. That's fine. It's not a memory</p> <p>3 test. That was a while back. Yes, sir.</p> <p>4 Have you done any work for that</p> <p>5 attorney since Actos? 11:52 AM</p> <p>6 A. No.</p> <p>7 Q. Do you know how the attorneys in</p> <p>8 this case got your name to call you?</p> <p>9 A. I think it was through a colleague</p> <p>10 they were working with who had known me. 11:52 AM</p> <p>11 Q. An attorney colleague?</p> <p>12 A. Yeah.</p> <p>13 Q. Yes, sir.</p> <p>14 When you were first contacted,</p> <p>15 what were you asked to do? 11:52 AM</p> <p>16 A. So I was asked to -- the question</p> <p>17 is, does NDMA or NDEA -- are they human</p> <p>18 carcinogens. That was -- that was kind of</p> <p>19 the basic first question, and then there are</p> <p>20 a couple -- you know, if it was a carcinogen, 11:52 AM</p> <p>21 what would be the mechanisms of action, what</p> <p>22 would be -- if it was a carcinogen, latency</p> <p>23 periods, and to look into potential tumor</p> <p>24 types.</p> <p>25 Q. Yes, sir. 11:53 AM</p>	<p style="text-align: right;">Page 133</p> <p>1 So my question to that is, at the</p> <p>2 time you were asked that question, did you</p> <p>3 have any understanding yourself what that</p> <p>4 answer is?</p> <p>5 A. No. So part of the scientific 11:54 AM</p> <p>6 process that we do for any scientific</p> <p>7 question is start from the base and just --</p> <p>8 there's a process we go through, and that</p> <p>9 process is just first getting -- let me go</p> <p>10 into -- 11:54 AM</p> <p>11 Q. No, no. I was just -- that first</p> <p>12 stage is where I'm kind of focused?</p> <p>13 A. Okay.</p> <p>14 Q. Did you learn, when you started to</p> <p>15 look into it, that there is no scientific 11:54 AM</p> <p>16 study that has established NDMA or NDEA cause</p> <p>17 cancer in humans?</p> <p>18 MR. NIGH: Form --</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. Did you learn that when you first 11:55 AM</p> <p>21 started?</p> <p>22 MR. NIGH: Form objection.</p> <p>23 MR. FOWLER: Yeah, that's a</p> <p>24 terrible question. Let me back up.</p> <p>25 / 11:55 AM</p>

<p style="text-align: right;">Page 134</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. You've never seen, in the course</p> <p>3 of your research for this, any article that</p> <p>4 has determined NDMA or NDEA is a human</p> <p>5 carcinogen, as opposed to, like EPA says, a 11:55 AM</p> <p>6 probable human carcinogen?</p> <p>7 A. Right. So part of my process, I</p> <p>8 looked for randomized control trials in</p> <p>9 humans. It's kind of the gold standard. And</p> <p>10 because it is a carcinogen, it would be 11:55 AM</p> <p>11 unethical to perform those in people, so.</p> <p>12 Q. Yes, sir. So am I correct that,</p> <p>13 even sitting here today, there's no</p> <p>14 publication that has conclusively found NDMA</p> <p>15 at low levels is a human carcinogen, correct? 11:55 AM</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A. So as I said before --</p> <p>18 BY MR. FOWLER:</p> <p>19 Q. Can we -- can we answer mine and</p> <p>20 then explain? 11:56 AM</p> <p>21 A. Oh, okay.</p> <p>22 Q. Because I just have to hear an</p> <p>23 answer.</p> <p>24 A. Correct. There's not one</p> <p>25 publication because there are no randomized 11:56 AM</p>	<p style="text-align: right;">Page 136</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. And is it fair to say that you've</p> <p>3 never been contacted by a drug company to</p> <p>4 assist them in research?</p> <p>5 A. Correct. 11:57 AM</p> <p>6 Q. Have you ever received or reviewed</p> <p>7 any of the medical records of any of the</p> <p>8 plaintiffs in this lawsuit?</p> <p>9 A. No.</p> <p>10 Q. Do you have any -- okay. 11:57 AM</p> <p>11 Doctor, and aside from this</p> <p>12 litigation, you've testified, I think --</p> <p>13 previously, you'd said, in the Actos</p> <p>14 litigation, how many depositions?</p> <p>15 A. Yeah, and then one other 11:58 AM</p> <p>16 deposition.</p> <p>17 Q. So two in Actos --</p> <p>18 A. Yeah.</p> <p>19 Q. -- and there was one in -- it was</p> <p>20 like -- it starts with a K? 11:58 AM</p> <p>21 A. Yes. That was -- that was related</p> <p>22 to Actos. And then, the other deposition I</p> <p>23 had was related to a stress-induced cancer</p> <p>24 case.</p> <p>25 Q. And that was -- the stress in that 11:58 AM</p>
<p style="text-align: right;">Page 135</p> <p>1 control trials with NDMA/NDEA. However, in</p> <p>2 science, we use an overabundant extensive</p> <p>3 literature search and look for whole bodies</p> <p>4 of evidence.</p> <p>5 So we'll look at animal studies; 11:56 AM</p> <p>6 we'll look at mechanistic evidence with</p> <p>7 animal tissue and cells; we'll look at human</p> <p>8 tissue and cells; and then look at epi</p> <p>9 studies. And that -- well, I'll look at what</p> <p>10 the -- what the regulatory agencies, such as 11:56 AM</p> <p>11 IARC and others -- do you want me --</p> <p>12 Q. No. That's fine. Thank you. I</p> <p>13 appreciate that.</p> <p>14 Have you ever communicated with</p> <p>15 anybody at Teva Pharmaceuticals, either in 11:56 AM</p> <p>16 regard to this case or at any point in your</p> <p>17 career?</p> <p>18 A. No.</p> <p>19 Q. And if I ask you the same question</p> <p>20 for the various defendants you heard 11:56 AM</p> <p>21 announced earlier, Mylan or ZHP, same answer?</p> <p>22 A. Same.</p> <p>23 Q. Yes, sir.</p> <p>24 (Reporter clarification.)</p> <p>25 MR. FOWLER: Or ZHP. 11:57 AM</p>	<p style="text-align: right;">Page 137</p> <p>1 matter was grief?</p> <p>2 A. Yes, it was -- what -- the husband</p> <p>3 had been hit by a bus that was the fault of</p> <p>4 the bus company, and the wife had colon</p> <p>5 cancer, and it was the stress -- can stress 11:58 AM</p> <p>6 stimulate the cancer in that case.</p> <p>7 Q. Did she have colon cancer before</p> <p>8 or after this tragic event?</p> <p>9 A. I'd have to look specifically. I</p> <p>10 think it was before. 11:59 AM</p> <p>11 Q. Okay.</p> <p>12 A. Yeah, it was a question, does</p> <p>13 stress promote cancer.</p> <p>14 Q. Do you currently have any other</p> <p>15 legal matters, litigation matters under 11:59 AM</p> <p>16 review outside of the valsartan litigation?</p> <p>17 A. No, I've been focusing on this</p> <p>18 case.</p> <p>19 Q. It's kept you pretty busy, hasn't</p> <p>20 it? 11:59 AM</p> <p>21 A. Yes.</p> <p>22 Q. Doctor, what percentage of your</p> <p>23 total income would you say is generated</p> <p>24 through legal consulting like you're doing in</p> <p>25 this case? 12:00 PM</p>

<p style="text-align: right;">Page 138</p> <p>1 A. Well, it can vary, really, year to</p> <p>2 year and over the years, depends on the year.</p> <p>3 If you talk to last two, three years --</p> <p>4 Q. Yes, sir.</p> <p>5 A. Yeah, I assume that. So maybe 12:00 PM</p> <p>6 about 50 percent, something like that.</p> <p>7 Q. Is it your testimony that as an</p> <p>8 assistant professor at Harvard Medical</p> <p>9 School, that your salary is more</p> <p>10 than \$500,000 a year? 12:00 PM</p> <p>11 MR. NIGH: Form objection.</p> <p>12 BY MR. FOWLER:</p> <p>13 Q. You're not saying that, are you?</p> <p>14 A. Wait, what's --</p> <p>15 Q. Let me ask it -- 12:00 PM</p> <p>16 A. Yeah.</p> <p>17 Q. Because I don't want to pry as to</p> <p>18 your personnel income. I won't ask you that,</p> <p>19 but I'm going to ask you a range.</p> <p>20 A. Yeah. 12:00 PM</p> <p>21 Q. In your job as an assistant</p> <p>22 professor at the Department of Pathology at</p> <p>23 Beth Israel Deaconess hospital, is it your</p> <p>24 testimony that your salary is more</p> <p>25 than \$500,000 a year? 12:00 PM</p>	<p style="text-align: right;">Page 140</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. Okay. And would you say that you</p> <p>3 put the same amount of time and effort into</p> <p>4 your research and opinion in the Kahiabani</p> <p>5 case as you did in the DeQuo and the Allen 12:02 PM</p> <p>6 case?</p> <p>7 A. I think they were pretty similar.</p> <p>8 Q. Okay.</p> <p>9 A. Yeah.</p> <p>10 Q. And how much are you charging per 12:02 PM</p> <p>11 hour for your work on this case, sir?</p> <p>12 A. \$500 an hour.</p> <p>13 Q. And how do you keep track of your</p> <p>14 time when you're working? Let's just keep it</p> <p>15 about valsartan, please. How do you keep 12:02 PM</p> <p>16 track of your time? Electronically? Paper</p> <p>17 ledger? You tell me.</p> <p>18 A. Usually just a Word document where</p> <p>19 I'll just -- on my computer, just keep track</p> <p>20 of the hours, you know, the day, hours. 12:02 PM</p> <p>21 Q. Do you note what you do when</p> <p>22 you -- when you write down that time?</p> <p>23 A. What was that?</p> <p>24 Q. Do you say -- do you say what you</p> <p>25 do? You know, reviewing journal articles, 12:03 PM</p>
<p style="text-align: right;">Page 139</p> <p>1 A. No.</p> <p>2 MR. NIGH: Form objection.</p> <p>3 A. No.</p> <p>4 BY MR. FOWLER:</p> <p>5 Q. Prior to this case, Doctor, would 12:01 PM</p> <p>6 you agree, and I get this from your prior</p> <p>7 testimony, that in the Actos litigation you</p> <p>8 were paid in the range of \$200,000 for your</p> <p>9 work in that case?</p> <p>10 MR. NIGH: Form objection. 12:01 PM</p> <p>11 A. I'd have to look. It's been a</p> <p>12 while ago, yeah, the specific amounts.</p> <p>13 BY MR. FOWLER:</p> <p>14 Q. In the Kahiabani,</p> <p>15 K-a-h-i-a-b-a-n-i, deposition, that's the 12:01 PM</p> <p>16 stress case, right?</p> <p>17 A. Yes.</p> <p>18 Q. And do you recall testifying that</p> <p>19 in the Allan case you were paid</p> <p>20 about \$100,000 total, and the DeQuo case, you 12:01 PM</p> <p>21 were also paid around \$100,000?</p> <p>22 Does that sound familiar?</p> <p>23 A. That sounds reasonable, yeah.</p> <p>24 MR. NIGH: Form objection.</p> <p>25 / 12:02 PM</p>	<p style="text-align: right;">Page 141</p> <p>1 5.0 hours, stuff like that. Do you say what</p> <p>2 the task is?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. In general. So, like, if I'm</p> <p>5 reviewing a certain specific topic -- 12:03 PM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. Yes, sir?</p> <p>8 A. -- you know -- but, there's -- in</p> <p>9 this particular case, there is so many</p> <p>10 publications, you know, two carcinogens, you 12:03 PM</p> <p>11 know, 10 tumor types. We have 9 key</p> <p>12 characteristics so -- so --</p> <p>13 Q. I understand.</p> <p>14 But right now I'm focused on your</p> <p>15 timekeeping. 12:03 PM</p> <p>16 And do you -- is that a living</p> <p>17 document where you just keep adding to it</p> <p>18 each time? You go back to do some more time,</p> <p>19 you make a note on some Word document?</p> <p>20 A. Well, I keep track of the hours. 12:03 PM</p> <p>21 Q. That's what I'm talking about,</p> <p>22 sir.</p> <p>23 A. Yeah.</p> <p>24 MR. NIGH: Form objection.</p> <p>25 / 12:03 PM</p>

<p style="text-align: right;">Page 142</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. Is it all on the same document?</p> <p>3 A. No, they can be different</p> <p>4 documents.</p> <p>5 Q. And do you refer to those 12:03 PM</p> <p>6 documents when it comes time to invoice</p> <p>7 Mr. Nigh?</p> <p>8 A. Yes.</p> <p>9 Q. And do you still have those</p> <p>10 documents that you used to create your 12:04 PM</p> <p>11 invoices for Mr. Nigh or plaintiffs' counsel,</p> <p>12 whoever you send them to you?</p> <p>13 MR. NIGH: Form objection.</p> <p>14 A. Well, yeah, I have -- I keep track</p> <p>15 of the hours. But then, I have drafts of the 12:04 PM</p> <p>16 report that -- or -- that I'll work on.</p> <p>17 Is that what you're asking?</p> <p>18 BY MR. FOWLER:</p> <p>19 Q. I understand. I'm just focused on</p> <p>20 your hours. 12:04 PM</p> <p>21 A. Okay.</p> <p>22 Q. Because what I'm asking is, I</p> <p>23 would like a copy of that time sheet, if you</p> <p>24 will. I have your invoices. We're going to</p> <p>25 look at them in a minute. 12:04 PM</p>	<p style="text-align: right;">Page 144</p> <p>1 completeness. And I'd ask you to do that</p> <p>2 now, and is this a complete set of your</p> <p>3 invoices, sir?</p> <p>4 A. Yeah, yes.</p> <p>5 Q. And for the record, we have an 12:05 PM</p> <p>6 invoice, and you can follow along. It's</p> <p>7 8/6/19. Is that approximately when you were</p> <p>8 first contacted?</p> <p>9 A. Correct.</p> <p>10 Q. Okay. And then, you have 12:06 PM</p> <p>11 12/20/19, 1/17/20, 2/17/20, 3/4/20,</p> <p>12 5/20/20 -- 5/20 on 2020, 7/29/2020, 12/2/20,</p> <p>13 4/13/21, a little out of order, 2/28/21,</p> <p>14 5/31/21, and then finally, 7/7/21.</p> <p>15 Correct, sir? 12:06 PM</p> <p>16 A. Correct.</p> <p>17 Q. And we're sitting here. This is,</p> <p>18 like, September 9. Have you submitted any</p> <p>19 additional invoices since July 7th?</p> <p>20 A. No. 12:06 PM</p> <p>21 Q. Have you done additional work</p> <p>22 since July 7th?</p> <p>23 A. Yeah.</p> <p>24 Q. And can you ballpark for me how</p> <p>25 many hours? 12:06 PM</p>
<p style="text-align: right;">Page 143</p> <p>1 A. Right.</p> <p>2 Q. But I'm going to add to our list</p> <p>3 of things --</p> <p>4 A. Oh, okay.</p> <p>5 Q. -- to collect your time 12:04 PM</p> <p>6 tabulations --</p> <p>7 A. Okay.</p> <p>8 Q. -- okay?</p> <p>9 A. Yes, yeah.</p> <p>10 MR. FOWLER: Let's mark Exhibit 6, 12:04 PM</p> <p>11 please.</p> <p>12 (Exhibit 6, Letter to Ned McWilliams from</p> <p>13 Dipak Panigrahy, M.D., marked for</p> <p>14 identification.)</p> <p>15 MR. FOWLER: Two copies coming 12:04 PM</p> <p>16 across.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. Sir, I'm presenting you with</p> <p>19 Exhibit 6, which I would submit is a</p> <p>20 collection of all of the invoices that were 12:05 PM</p> <p>21 provided on September 7th as part of the</p> <p>22 production from the plaintiffs' steering</p> <p>23 committee.</p> <p>24 Feel free, as with anything I put</p> <p>25 in front of you, to look at it for 12:05 PM</p>	<p style="text-align: right;">Page 145</p> <p>1 A. Maybe about 30, 40 hours,</p> <p>2 something like that.</p> <p>3 Q. Okay. And of that 30 or 40 hours</p> <p>4 since July, how much of that time has been</p> <p>5 spent meeting either in-person or remotely 12:07 PM</p> <p>6 with plaintiffs' counsel?</p> <p>7 A. A few hours doing Zoom. Most of</p> <p>8 the time, it's just reading and getting the</p> <p>9 papers together and --</p> <p>10 Q. No, I understand. My question was 12:07 PM</p> <p>11 super narrow, how much time you've spent with</p> <p>12 plaintiffs' counsel since July.</p> <p>13 A. So I think we had a few Zoom -- a</p> <p>14 few hours. Maybe, like, an hour or two every</p> <p>15 couple weeks, something like that. 12:07 PM</p> <p>16 Q. Yes, sir. And of these invoices,</p> <p>17 I think I had 12 total, have they all been</p> <p>18 paid, sir?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And we're going to look 12:07 PM</p> <p>21 closer at these, and you can check my math,</p> <p>22 but in total so far, you've billed \$710,000,</p> <p>23 and according to you, you've been paid</p> <p>24 \$710,000?</p> <p>25 A. Correct. 12:08 PM</p>

<p style="text-align: right;">Page 146</p> <p>1 Q. And when I asked you earlier what 2 percentage of your income was from legal 3 consulting, you said 50 percent. 4 Isn't the answer something else? 5 MR. NIGH: Form objection. 12:08 PM 6 A. My understanding, you were saying 7 in general, like -- 8 (Reporter clarification.) 9 THE WITNESS: My recollection, you 10 were asking in general, like over the 12:08 PM 11 last decade in general, you know, not -- 12 not in the last year. 13 BY MR. FOWLER: 14 Q. We can agree that the 710,00 that 15 you've been paid since August of 2019 is a 12:08 PM 16 magnitude over what your salary is as an 17 assistant professor? 18 A. Correct. 19 Q. It could be -- and I'm not going 20 to ask, but it could be at least twice as 12:08 PM 21 much that you -- 22 MR. NIGH: Form objection. We're 23 getting -- 24 MR. FOWLER: Yes, sir. 25 MR. NIGH: -- into salary. Don't 12:08 PM</p>	<p style="text-align: right;">Page 148</p> <p>1 Q. And would I also be correct that 2 you don't give a haircut -- let me strike -- 3 You don't give a reduction on any 4 of the other subsequent bills, do you? 5 A. Correct. 12:10 PM 6 Q. What was behind your -- what was 7 behind that -- those two sentences where you 8 agreed to give up -- my math is slow; bear 9 with me -- \$22,000 off of this bill? 10 A. Well, I think the first invoice 12:10 PM 11 was very early, just starting to study the 12 case, and it wasn't until later where -- you 13 know, when I started to spend more time, you 14 know, that's when -- 15 Q. Well, Doctor, you spent time. 12:10 PM 16 According to you, you spent 74 hours here 17 early in the case for a total of \$37,000, but 18 you were only asking for 15. 19 And my question is, why? 20 A. At the -- in the initial part of 12:11 PM 21 the case, like this very first invoice, I was 22 more also reading on my own. So I didn't 23 want to bill for some extra hours as I 24 started to learn the case. 25 Q. Okay. 12:11 PM</p>
<p style="text-align: right;">Page 147</p> <p>1 answer that question. 2 BY MR. FOWLER: 3 Q. And looking -- let me start that 4 again. 5 When you were first contacted 12:09 PM 6 with -- by plaintiffs' counsel in 2019, did 7 you have any sort of an agreement with them 8 with regard to your fees, other than your 9 hourly rate? Was there any kind of fee cap? 10 Fee structure? Incentive fees? Anything? 12:09 PM 11 A. No. We were saying we could bill 12 every couple months. That was about the 13 only -- 14 Q. Okay. You didn't agree to cap 15 your fees at any amount, apparently, right? 12:09 PM 16 A. No. 17 Q. And looking at page 1 of this 18 exhibit, the August 6th, 2019, invoice, the 19 end of the first paragraph you say, "I spent 20 a total of 74 hours at the agreed-upon rate 12:09 PM 21 of 500 an hour, which would equal 37,000. I 22 only intend to bill for 30 hours at 500 an 23 hour for 15,000." 24 Did I read that correctly. 25 A. Correct. 12:10 PM</p>	<p style="text-align: right;">Page 149</p> <p>1 A. So early on, I didn't know where 2 it was going, how it -- you know, how 3 extensive it was going to be, so. 4 Q. So, then, why do you make a point 5 of noting that you spent 74, not 75 or 70 -- 12:11 PM 6 it was a very specific number -- 74 hours, 7 but you only want to bill for 30? 8 A. That's probably -- 74 is probably 9 the actual time -- that's the time I spent. 10 Q. Well, that's what you said. 12:11 PM 11 A. Yeah. But what it's saying is 12 that some of that 74 hours, and for the first 13 invoice, is looking, in general, at the case. 14 Q. Is this like your promotional 15 offer or something, where it's a one-time 12:11 PM 16 deal? You know, I don't understand. I 17 mean -- 18 MR. NIGH: Form objection. 19 Mischaracterizes testimony. 20 BY MR. FOWLER: 12:12 PM 21 Q. You could have had plaintiffs' pay 22 for that time and given the money to charity 23 or something, right? 24 MR. NIGH: Form objection. 25 A. At the time, I just thought I 12:12 PM</p>

<p style="text-align: right;">Page 150</p> <p>1 would only bill for the 30 hours. Because if 2 it's the first invoice, I thought -- 3 initially, I wasn't sure how much time I was 4 going to spend, and for the first invoice, it 5 just seemed that was like a reasonable thing 12:12 PM 6 to do. 7 BY MR. FOWLER: 8 Q. Were you maybe concerned that you 9 might price yourself out of this litigation 10 if you billed the whole amount? 12:12 PM 11 MR. NIGH: Form objection. 12 A. No, I just wasn't sure how much of 13 a time commitment, how extensive it was going 14 to be. 15 Q. I don't understand that statement, 12:12 PM 16 sir. When, in this first month, you've 17 spent 74 hours, and you're telling me that 18 you didn't know how much time it was going to 19 take? Is that what I understand? 20 A. Yeah, I think initially, when you 12:12 PM 21 first study, you know, does a chemical cause 22 cancer, you do very overall concepts. 23 So in the initial stage for the 24 first, when I wasn't spending lots of hours, 25 you know, it was an initial survey of the 12:13 PM</p>	<p style="text-align: right;">Page 152</p> <p>1 Q. Well, I'm up to July 2020. 2 A. Okay. 3 Q. You're -- what you're saying is 4 that you were preparing your report then? 5 A. Correct. 12:14 PM 6 Q. And as of July 2020, a year before 7 your report was due, you had thus far 8 spent -- well, you'd received a total 9 of \$226,000 from plaintiffs as of July 2020. 10 Would you accept my math on that? 12:15 PM 11 A. Correct, yeah. 12 Q. And by the end of 2020, you had 13 worked a total of 519 hours on this case. 14 Does that sound correct? 15 A. Yes. 12:15 PM 16 Q. What I'm really -- well, strike 17 really. 18 Let me direct your attention to 19 May 31, 2021, bill. Are you with me? 20 A. Yes. 12:15 PM 21 Q. On that -- at the end of May 2021, 22 you had already received \$517,500 and your 23 bill for that month was 190 hours, correct? 24 A. Correct. 25 Q. And if you turn to July 7th, 2021, 12:16 PM</p>
<p style="text-align: right;">Page 151</p> <p>1 literature and just very initial downloading 2 of papers and, you know, starting to read. 3 So for a first invoice, it was -- 4 I just thought it was reasonable not to 5 charge the whole amount. 12:13 PM 6 Q. And for the next thousand hours 7 that you've spent on this case, you know, if 8 it wasn't reading about these things -- well, 9 let me strike that. I'll get back to that 10 thousand hours. 12:13 PM 11 Doctor, moving -- trying to move 12 this along, in December 2019, you billed 13 for 21 hours, correct, and in January 2020, 14 it was 58 hours? Is that what's reflected in 15 your invoice? 12:14 PM 16 A. Yes. 17 Q. And then the very next month, 52 18 hours. Do you see that? 19 A. Yes. 20 Q. And for each of these, and for 12:14 PM 21 each invoice in May, 2020, July, 2020, you 22 know, for 130 hours in May, 111 in July, you 23 say, "Preparing report." 24 Do you see that? 25 A. Which one are you on? 12:14 PM</p>	<p style="text-align: right;">Page 153</p> <p>1 your bill was for 386 hours preparing the 2 report, correct? 3 A. Correct. 4 Q. And so in six weeks -- forget my 5 math. Between the June 1 and July 7, you 12:16 PM 6 billed on average 77 hours a week on this 7 case. 8 Does my math sound right on that? 9 MR. NIGH: Form objection. 10 A. Correct. 12:16 PM 11 BY MR. FOWLER: 12 Q. And that was in writing your 13 report? 14 A. Correct. 15 Q. Did you take a sabbatical? Did 12:16 PM 16 you leave your day job? How were you 17 doing 77 hours a week on this report while 18 still being employed? 19 A. So my personal hours, I'm used to 20 working, starting as a surgery resident, 130 12:17 PM 21 hours a week. So what I do day-to-day is -- 22 when -- I'm used to working around the clock 23 and also with -- I was working a lot from 24 home, so I was working remotely, and we 25 just -- I'm used to doing multiple projects 12:17 PM</p>

<p style="text-align: right;">Page 154</p> <p>1 at the same time.</p> <p>2 But toward the end, when the</p> <p>3 report was due, last couple of months, that's</p> <p>4 when -- the last two months where it was --</p> <p>5 the hours definitely increased, because, as I 12:17 PM</p> <p>6 said before, this was two carcinogens with,</p> <p>7 you know, 60 years of literature to go</p> <p>8 through, with 10 tumor types, with, you</p> <p>9 know, 9 key characteristics, and so I just</p> <p>10 planned my schedule accordingly. 12:17 PM</p> <p>11 Q. Okay. So by May 31st, you had</p> <p>12 already spent over a thousand hours on this</p> <p>13 case and then we added another 386 hours by</p> <p>14 the time we got to July 7th, after your</p> <p>15 report was submitted? 12:18 PM</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A. Correct.</p> <p>18 BY MR. FOWLER:</p> <p>19 Q. Okay.</p> <p>20 MR. NIGH: Mr. Fowler, how much 12:18 PM</p> <p>21 longer do you want to go before lunch</p> <p>22 break?</p> <p>23 MR. FOWLER: 15 minutes, maybe.</p> <p>24 We'll just do one more line of</p> <p>25 questioning and then take a break. Good 12:18 PM</p>	<p style="text-align: right;">Page 156</p> <p>1 question mark there. By Dr. Fishbein,</p> <p>2 Dr. Hammock, Dr. Serhan and Dr. Panigrahy.</p> <p>3 You were the fourth author on</p> <p>4 this?</p> <p>5 A. Yes. 12:19 PM</p> <p>6 Q. And would this be one of those</p> <p>7 other multitasking projects that you were</p> <p>8 working on at the same time as the report?</p> <p>9 A. Correct.</p> <p>10 Q. And would I be correct, Doctor, 12:20 PM</p> <p>11 that a lot of statements that are contained</p> <p>12 in your publication are likewise appearing in</p> <p>13 your report in this case?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 BY MR. FOWLER: 12:20 PM</p> <p>16 Q. Correct, Doctor?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 A. No, this paper -- the report was</p> <p>19 focused on valsartan and contaminated NDMA.</p> <p>20 This was more a review of carcinogenesis in 12:20 PM</p> <p>21 general. There may be some overlapping</p> <p>22 concepts, but this review focused more on</p> <p>23 inflammation in cancer and carcinogenesis --</p> <p>24 BY MR. FOWLER:</p> <p>25 Q. And that is one of your opinions 12:20 PM</p>
<p style="text-align: right;">Page 155</p> <p>1 point, sir.</p> <p>2 MR. NIGH: Okay.</p> <p>3 MR. FOWLER: I am marking</p> <p>4 Exhibit 8, I hope.</p> <p>5 THE REPORTER: 7. 12:19 PM</p> <p>6 (Exhibit 7, Elsevier, attached</p> <p>7 Carcinogenesis: Failure of resolution of</p> <p>8 inflammation?, marked for identification.)</p> <p>9 MR. FOWLER: I've got two copies</p> <p>10 coming over. 12:19 PM</p> <p>11 THE REPORTER: Just for counsel, I</p> <p>12 have this as Exhibit 7.</p> <p>13 MR. FOWLER: Thank you.</p> <p>14 THE REPORTER: Hold on.</p> <p>15 MR. FOWLER: I'm just giving these 12:19 PM</p> <p>16 to counsel.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. Dr. Panigrahy, before you is</p> <p>19 what's been marked Exhibit 7. Do you</p> <p>20 recognize this -- this article? 12:19 PM</p> <p>21 A. Yes.</p> <p>22 Q. And for the record, this is a</p> <p>23 publication in Pharmacology & Therapeutics in</p> <p>24 2021 called, "Carcinogenesis: Failure of</p> <p>25 resolution of inflammation?" There's a 12:19 PM</p>	<p style="text-align: right;">Page 157</p> <p>1 in this case, is inflammation in cancer, sir,</p> <p>2 isn't it?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. So this -- that is one topic</p> <p>5 that's common. 12:21 PM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. That's right. This article about</p> <p>8 inflammation and cancer, you also have --</p> <p>9 that's a bad start to a question.</p> <p>10 Your report has an entire section 12:21 PM</p> <p>11 expressing opinions about inflammation and</p> <p>12 tumor initiation, promotion, and progression,</p> <p>13 in your report, correct, sir?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. Right, the concept. 12:21 PM</p> <p>16 BY MR. FOWLER:</p> <p>17 Q. And those same concepts are in</p> <p>18 this article, correct?</p> <p>19 A. So this -- yes, there's some</p> <p>20 overlap. 12:21 PM</p> <p>21 Q. Correct. And what my question</p> <p>22 was -- there are literally statements taken</p> <p>23 directly out of this article. Let me, for</p> <p>24 example, direct your attention to page 4,</p> <p>25 second column, last paragraph, halfway down 12:21 PM</p>

<p style="text-align: right;">Page 158</p> <p>1 the last paragraph, sir, you see a sentence 2 that begins "Thus chemicals"? It's about ten 3 lines up from the bottom. 4 "Thus, chemicals that are 5 carcinogenic via genotoxicity to rodents, are 12:22 PM 6 presumed to be carcinogenic to humans unless 7 proven otherwise." 8 That statement, do you recognize 9 as also appearing in your report, sir? 10 A. Yes. 12:22 PM 11 Q. Okay. Thank you. 12 And there are other statements or 13 conclusions in this study that you also make 14 in your report with regard to the mechanism 15 of inflammation, tumor initiation, promotion, 12:22 PM 16 or progression, correct? 17 MR. NIGH: Form objection. 18 A. Well, yes, there's some -- 19 BY MR. FOWLER: 20 Q. Okay. 12:22 PM 21 A. -- like inflammation can promote 22 cancer, so that, we talked about in the 23 review and I talk about in here. 24 Q. That's right. 25 And, Doctor, let me direct your 12:22 PM</p>	<p style="text-align: right;">Page 160</p> <p>1 (Reporter clarification.) 2 THE WITNESS: Induce -- or cause 3 human cancer. Does contaminated NDMA 4 and NDEA in valsartan cause human 5 cancer. 12:24 PM 6 This review doesn't talk about 7 valsartan. It doesn't -- this is not 8 about -- focus on NDMA and NDEA. 9 This review is about inflammation 10 and cancer, and it's a review on other 12:24 PM 11 people's work. There's no original data 12 in here. And it's not a competing 13 interest because this -- it did not -- 14 this report did not affect the 15 objectivity or interpretation of this 12:24 PM 16 review. 17 BY MR. FOWLER: 18 Q. You don't see a conflict of 19 interest having been paid a half million 20 dollars for an opinion that inflammation 12:24 PM 21 causes cancer and then you turn around and 22 publish in a peer-reviewed article 23 inflammation causes cancer, and you don't 24 tell anybody you've been paid a half a 25 million dollars for that same opinion? 12:25 PM</p>
<p style="text-align: right;">Page 159</p> <p>1 attention to the last page of the article. 2 It's page 23. It's before the references. 3 Are you with me, sir? 4 A. Yes. 5 Q. You see the section, declaration 12:23 PM 6 of competing interest? 7 A. Correct. 8 Q. And what does it say under there? 9 A. Yeah, authors declare no conflict 10 of interest. 12:23 PM 11 Q. At the time this was published, 12 Doctor, you had been paid over \$500,000 from 13 the plaintiffs in this case where you were 14 offering the exact same opinion as reflected 15 in this article that was published a year and 12:23 PM 16 a half after you were retained; isn't that 17 correct? 18 A. No. 19 MR. NIGH: Form objection. 20 A. No. So a competing interest is 12:23 PM 21 anything that influences the objectivity or 22 the interpretation of a review. This report 23 was -- asked a question, does contaminated 24 NDMA and NDMA [sic] in valsartan cause human 25 cancer? There's no mention of -- 12:24 PM</p>	<p style="text-align: right;">Page 161</p> <p>1 A. No, this report does -- 2 MR. NIGH: Hold on. Hold on. 3 Hold on. Let me -- let me respond with 4 my form objection. You've got to slow 5 down a little. 12:25 PM 6 Form objection. 7 You can answer. 8 A. Oh. This report, I don't rely on 9 inflammation in cancer. The 9 key 10 characteristics -- it's not just inflammation 12:25 PM 11 in cancer. I rely on oxidative stress. I 12 rely on genotoxicity, on NDMA-inducing 13 mutagenic activity. So this report doesn't 14 compete with this review. 15 BY MR. FOWLER: 12:25 PM 16 Q. Doctor, you have an entire section 17 in the report that you were paid for that 18 offers an opinion that inflammation, as a 19 result of -- as a result of NDMA, that 20 inflammation causes -- initiates or promotes 12:25 PM 21 or causes cancer to progress. You have an 22 entire section labeled inflammation in your 23 report, don't you? 24 A. And I've cited -- 25 MR. NIGH: Hold on. Hold on. 12:26 PM</p>

<p style="text-align: right;">Page 162</p> <p>1 Form objection.</p> <p>2 You can answer.</p> <p>3 A. In science, I've cited -- that</p> <p>4 inflammation promotes cancer is a well-known</p> <p>5 study concept known in the 1970s, '80s. It's 12:26 PM</p> <p>6 been cited for 50 years. I cite that in here</p> <p>7 and in the review. That's not -- that's not</p> <p>8 relevant to the opinions here that -- does</p> <p>9 contaminated valsartan cause human cancer</p> <p>10 through NDMA and NDEA. 12:26 PM</p> <p>11 The review of a field is just</p> <p>12 taking other people's papers and saying</p> <p>13 here's what's known about cancer and</p> <p>14 inflammation, and I cite in all the -- this</p> <p>15 review has over 600 references. I've cited 12:26 PM</p> <p>16 the people's work. There's no opinions here.</p> <p>17 This is -- this is just citing a review of</p> <p>18 the cancer field.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. Which is exactly what you do in 12:26 PM</p> <p>21 your report, isn't it?</p> <p>22 A. No, the report is offering an</p> <p>23 opinion, my opinion, on does NDMA and NDEA</p> <p>24 cause cancer.</p> <p>25 Q. Yes, but based upon your review of 12:27 PM</p>	<p style="text-align: right;">Page 164</p> <p>1 conclusion, isn't it, sir?</p> <p>2 MR. NIGH: Form objection.</p> <p>3 A. This is just a review on the</p> <p>4 field. This is not any original paper. This</p> <p>5 is -- this is citing a field and just saying, 12:28 PM</p> <p>6 here is what people have shown --</p> <p>7 BY MR. FOWLER:</p> <p>8 Q. Yes, sir.</p> <p>9 A. -- and documenting it.</p> <p>10 Q. Yes, sir. On page 6 of this 12:28 PM</p> <p>11 article, in the bottom of the second column,</p> <p>12 all the way at the bottom, last paragraph,</p> <p>13 the paragraph is, nitrosamines, including</p> <p>14 NDMA and NDEA, play a critical role in the</p> <p>15 initiation stage of carcinogenesis. 12:28 PM</p> <p>16 Do you see that, sir?</p> <p>17 A. Yes.</p> <p>18 Q. That is exactly what you have</p> <p>19 written in your report, isn't it?</p> <p>20 MR. NIGH: Form objection. 12:28 PM</p> <p>21 A. So, like I said, the concept of --</p> <p>22 this is answered in the question of</p> <p>23 contaminated NDMA/NDEA in valsartan.</p> <p>24 THE REPORTER: The concept and</p> <p>25 then what? 12:29 PM</p>
<p style="text-align: right;">Page 163</p> <p>1 all of the things that you've said you were</p> <p>2 reviewing, right?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. But I'm reviewing the concept</p> <p>5 relevant to this question. 12:27 PM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. Yes, sir, and in that review --</p> <p>8 you didn't do any original laboratory</p> <p>9 testing, any original calculations, any</p> <p>10 original lab research yourself to arrive at 12:27 PM</p> <p>11 your opinions. You reviewed the literature</p> <p>12 and studies that were available, correct,</p> <p>13 sir?</p> <p>14 A. Right.</p> <p>15 MR. NIGH: Hold on. Hold on. 12:27 PM</p> <p>16 Form objection.</p> <p>17 A. This report did not influence the</p> <p>18 objectivity or interpretation of any of the</p> <p>19 material in this review.</p> <p>20 BY MR. FOWLER: 12:27 PM</p> <p>21 Q. If this review had concluded</p> <p>22 that -- well, first of all, this review</p> <p>23 doesn't conclude definitively that</p> <p>24 inflammation initiates, promotes, or</p> <p>25 progresses. It simply may. That's the 12:28 PM</p>	<p style="text-align: right;">Page 165</p> <p>1 THE WITNESS: Yeah, this question</p> <p>2 of whether NDMA or NDEA in valsartan</p> <p>3 causes human cancer is different from a</p> <p>4 review where we're just objectively</p> <p>5 citing the literature, and there's no 12:29 PM</p> <p>6 opinions here.</p> <p>7 BY MR. FOWLER:</p> <p>8 Q. Doctor, in that paragraph -- and</p> <p>9 if you'd like, I will isolate these on the</p> <p>10 break -- every sentence that appears in that 12:29 PM</p> <p>11 bottom paragraph is in your report.</p> <p>12 IARC, I-A-R-C, has classified NDMA</p> <p>13 and NDEA as probable carcinogens, Group 2A.</p> <p>14 That statement's in your report,</p> <p>15 yes? 12:29 PM</p> <p>16 MR. NIGH: Form objection.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. Yes?</p> <p>19 A. Correct.</p> <p>20 Q. The next one, NDMA induces cancer 12:29 PM</p> <p>21 vis-a-vis a dose response, Peto, Gray,</p> <p>22 Brantom, Grasso. That statement and those</p> <p>23 references, also in your report, correct,</p> <p>24 sir?</p> <p>25 MR. NIGH: Form objection. 12:29 PM</p>

<p style="text-align: right;">Page 166</p> <p>1 A. Correct.</p> <p>2 BY MR. FOWLER:</p> <p>3 Q. The sentence, the very sentence,</p> <p>4 NDMA has demonstrated highly carcinogenic,</p> <p>5 mutagenic, and teratogenic activity. 12:30 PM</p> <p>6 That is in your report exactly as</p> <p>7 stated there, isn't it, sir?</p> <p>8 A. Correct.</p> <p>9 Q. And you were working on this</p> <p>10 article before, during, and after your 12:30 PM</p> <p>11 report?</p> <p>12 A. This is in the context of --</p> <p>13 Q. Strike that.</p> <p>14 A. -- a review. Correct. This is in</p> <p>15 a context of a review of the literature, and 12:30 PM</p> <p>16 this -- citing it in this report is answering</p> <p>17 a question, like I said before, does NDMA or</p> <p>18 NDEA in valsartan cause human cancer. This</p> <p>19 review doesn't talk about valsartan, doesn't</p> <p>20 offer an opinion. 12:30 PM</p> <p>21 This report offers an opinion</p> <p>22 related to valsartan. So there's no</p> <p>23 competing interest between this and an</p> <p>24 objective review here where I don't offer an</p> <p>25 opinion on valsartan. 12:30 PM</p>	<p style="text-align: right;">Page 168</p> <p>1 anybody that?</p> <p>2 A. Like I said --</p> <p>3 MR. NIGH: Hold on. Hold on.</p> <p>4 Form objection.</p> <p>5 A. Okay. Because this is not a 12:31 PM</p> <p>6 competing interest, didn't affect the</p> <p>7 objectivity and interpretation of this</p> <p>8 review. We state scientific facts and then</p> <p>9 cite them. There's no opinions in this</p> <p>10 review that's related to the report, so. 12:31 PM</p> <p>11 BY MR. FOWLER:</p> <p>12 Q. So from your objectivity, you</p> <p>13 weren't trying to make sure -- well, strike</p> <p>14 that.</p> <p>15 And needless to say, you didn't 12:31 PM</p> <p>16 inform the editors of your engagement with</p> <p>17 plaintiffs on NDMA, correct?</p> <p>18 A. Correct, because there wasn't a</p> <p>19 competing interest.</p> <p>20 Q. And is it your testimony that 12:32 PM</p> <p>21 you've never seen a journal article where, in</p> <p>22 the conflicts of interest, the authors say</p> <p>23 they're working with a pharmaceutical company</p> <p>24 or they're working in this litigation; have</p> <p>25 you ever seen that before? 12:32 PM</p>
<p style="text-align: right;">Page 167</p> <p>1 Q. Doctor, you don't offer an opinion</p> <p>2 on valsartan in your report. You offered an</p> <p>3 opinion on NDMA. I thought we covered that</p> <p>4 question.</p> <p>5 MR. NIGH: Form objection. 12:30 PM</p> <p>6 A. Correct.</p> <p>7 BY MR. FOWLER:</p> <p>8 Q. Withdrawn.</p> <p>9 Doctor, did you tell Dr. Fishbein</p> <p>10 that you've been hired by plaintiffs in the 12:31 PM</p> <p>11 valsartan litigation and have been paid a</p> <p>12 half a million dollars to talk about</p> <p>13 inflammation and cancer in your report?</p> <p>14 Did you tell Fishbein that?</p> <p>15 A. It's -- 12:31 PM</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A. Because it's not a competing</p> <p>18 interest, I didn't have to tell --</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. So you didn't tell Dr. Fishbein. 12:31 PM</p> <p>21 Did you tell any of the other</p> <p>22 authors that at the same time you were</p> <p>23 getting paid a half a million dollars to talk</p> <p>24 about the subject, like we looked on page 6,</p> <p>25 nitrosamines and cancer -- did you tell 12:31 PM</p>	<p style="text-align: right;">Page 169</p> <p>1 A. Yes.</p> <p>2 MR. NIGH: Form objection.</p> <p>3 BY MR. FOWLER:</p> <p>4 Q. Why do you think they did that?</p> <p>5 A. So if there was a competing 12:32 PM</p> <p>6 interest, then you do it. If this review was</p> <p>7 on contaminated NDMA and valsartan and I was</p> <p>8 giving an opinion, then yes.</p> <p>9 Q. And you didn't -- if you think</p> <p>10 it's not a competing interest and no conflict 12:32 PM</p> <p>11 of interest, why not tell the lead author of</p> <p>12 what you're doing to make sure, before they</p> <p>13 put their name on this paper and sign off on</p> <p>14 conflict of interest, that they agree with</p> <p>15 you? 12:33 PM</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A. Because it wasn't relevant to,</p> <p>18 like I said, having a competing interest.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. And so do you think that this 12:33 PM</p> <p>21 journal is going to agree with you, that</p> <p>22 there's not a conflict of interest?</p> <p>23 MR. NIGH: Form objection.</p> <p>24 A. Yeah.</p> <p>25 / 12:33 PM</p>

<p style="text-align: right;">Page 170</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. If -- let me rephrase.</p> <p>3 If the journal were to learn that</p> <p>4 you are in this litigation, do you think they</p> <p>5 would agree? 12:33 PM</p> <p>6 A. Yes --</p> <p>7 MR. NIGH: Form objection.</p> <p>8 A. -- because, like I said, I'm</p> <p>9 not -- this doesn't affect the interpretation</p> <p>10 or objectivity of this review. 12:33 PM</p> <p>11 BY MR. FOWLER:</p> <p>12 Q. Would you agree, Doctor, that</p> <p>13 what's stated in this review is completely</p> <p>14 consistent with what's stated in your report?</p> <p>15 MR. NIGH: Form objection. 12:33 PM</p> <p>16 A. There's some concepts that are --</p> <p>17 there are overlapping. That's because, in</p> <p>18 science, you talk about, like, in the key</p> <p>19 characteristics -- of the 10 key</p> <p>20 characteristics, inflammation is one of the 12:34 PM</p> <p>21 10 key characteristics.</p> <p>22 But this report, I go much more</p> <p>23 into characteristic 1, electrophilic, you</p> <p>24 know, metabolic activation, genotoxicity, you</p> <p>25 know; key characteristic 3, DNA repair, 12:34 PM</p>	<p style="text-align: right;">Page 172</p> <p>1 report labeled "Inflammation," and only that</p> <p>2 section, do you agree that this article is</p> <p>3 entirely consistent with what you've stated</p> <p>4 in your report, or do you contend that this</p> <p>5 is entirely consistent, is a better question? 12:35 PM</p> <p>6 MR. NIGH: Form objection.</p> <p>7 A. I agree there's consistency</p> <p>8 because in science there's certain concepts</p> <p>9 that I've cited in the review, and I cited in</p> <p>10 the report that are known, like inflammation 12:35 PM</p> <p>11 can promote cancer; so those are cited.</p> <p>12 But as I said before, in the</p> <p>13 report I was asked a question related to</p> <p>14 contaminated valsartan with NDMA and NDEA.</p> <p>15 And this review is a review on the field of 12:35 PM</p> <p>16 carcinogenesis and cancer. So there was no</p> <p>17 competing interest between this report and</p> <p>18 this review.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. Thank you, Doctor. 12:35 PM</p> <p>21 MR. FOWLER: Let's take lunch.</p> <p>22 Time, Mr. Nigh?</p> <p>23 MR. NIGH: Okay.</p> <p>24 THE VIDEOGRAPHER: The time is</p> <p>25 12:35. We're off the record. 03:48 PM</p>
<p style="text-align: right;">Page 171</p> <p>1 genomic instability, you know; key</p> <p>2 characteristic 4 --</p> <p>3 Q. Sure.</p> <p>4 A. -- you know, and on and on.</p> <p>5 Q. Sure. Let me rephrase -- 12:34 PM</p> <p>6 MR. NIGH: We've been going --</p> <p>7 we've been going more than 15 minutes --</p> <p>8 MR. FOWLER: I know. One more</p> <p>9 question we'll take the break -- well,</p> <p>10 it's been 17, Counsel. 12:34 PM</p> <p>11 One more question on this.</p> <p>12 MR. NIGH: What I said was right.</p> <p>13 We have been going for more than 15</p> <p>14 minutes. I didn't get to finish my</p> <p>15 statement. You interrupted me. I said 12:34 PM</p> <p>16 how much longer do you have? That's</p> <p>17 what I was going to ask.</p> <p>18 MR. FOWLER: I'm just going to</p> <p>19 finish this document.</p> <p>20 MR. NIGH: Okay. 12:34 PM</p> <p>21 MR. FOWLER: With my last</p> <p>22 question, if I now keep it -- get it</p> <p>23 back in my head.</p> <p>24 BY MR. FOWLER:</p> <p>25 Q. Focusing on the section of your 12:34 PM</p>	<p style="text-align: right;">Page 173</p> <p>1 (Recess taken at 12:35 p.m. to 1:45 p.m.)</p> <p>2 THE VIDEOGRAPHER: The time is</p> <p>3 1:45. We're back on the record.</p> <p>4 BY MR. FOWLER:</p> <p>5 Q. Welcome back. I hope everyone had 01:46 PM</p> <p>6 a nice lunch.</p> <p>7 Couple wrap-up questions, Doctor,</p> <p>8 on the Fishbein article we were talking</p> <p>9 about.</p> <p>10 Am I correct, Doctor, that you 01:46 PM</p> <p>11 cite to this article in your report several</p> <p>12 times?</p> <p>13 A. Correct.</p> <p>14 Q. Okay. And within this article,</p> <p>15 sir, if I could direct your attention to 01:46 PM</p> <p>16 page 7. It's the top of the first column at</p> <p>17 the bottom of that first paragraph, you have</p> <p>18 a sentence there that says "NDMA causes</p> <p>19 cancer both as a single dose and with</p> <p>20 long-term exposure to lower quantities." 01:47 PM</p> <p>21 And you cite to the Pottgard,</p> <p>22 2018 study as your reference there.</p> <p>23 Do you see that, sir?</p> <p>24 A. Correct.</p> <p>25 Q. Do you recall what the Pottgard 01:47 PM</p>

<p style="text-align: right;">Page 174</p> <p>1 study actually found with regard to the 2 incidence of cancer? 3 MR. NIGH: Form objection. 4 A. Yeah. Yes. 5 BY MR. FOWLER: 01:47 PM 6 Q. And is this a mistake? 7 A. So part of referencing in science, 8 when we have 600 references, yeah, that 9 reference should be with a couple other 10 references. And so of the 600 or whatever 01:47 PM 11 references we had in this -- that could have 12 been -- yeah, there should be a different 13 reference in addition -- you know, sometimes 14 we reference a paper that will say, you know, 15 will -- may say that, but I should have put 01:48 PM 16 another reference in. 17 Q. Because it sounds like you would 18 agree that the Pottegard study actually did 19 not find a statistically significant increase 20 in any of the cancers as a result of NDMA, 01:48 PM 21 correct? 22 MR. NIGH: Form objection. 23 A. Correct. Like I said, like, when 24 we do our paper with 600 references, which is 25 a little unusual, this is a review; so in 01:48 PM</p>	<p style="text-align: right;">Page 176</p> <p>1 statement that you attributed to 2 Dr. Pottegard was inaccurate? 3 A. Just now, when I looked at it. 4 But, like I said, before, when we write these 5 references, taken in the context of 600 01:49 PM 6 references. So there are other references 7 that refer to this statement -- 8 Q. Okay. 9 A. -- that are right in that 10 paragraph. 01:50 PM 11 Q. Okay. Thank you, and you can set 12 that aside. I appreciate that. 13 Switching gears, now let's talk 14 about your report, sir. 15 When you prepared that report for 01:50 PM 16 this litigation, you attempted to provide the 17 basis for each of the opinions contained in 18 that report, correct? 19 A. Correct. 20 Q. And can we -- do you agree that 01:50 PM 21 your report contains all of the opinions you 22 intend to offer in this case? 23 MR. NIGH: Form objection. 24 A. Yes, the opinions that I have are 25 in this report. 01:50 PM</p>
<p style="text-align: right;">Page 175</p> <p>1 there, in that same paragraph there will be 2 multiple references before and after that 3 apply to this sentence, so the references 4 before are the ones that -- it refers to that 5 statement. 01:49 PM 6 BY MR. FOWLER: 7 Q. And when did you realize this 8 mistake in the paper? Was it in preparation 9 for this deposition? 10 MR. NIGH: Form objection. 01:49 PM 11 BY MR. FOWLER: 12 Q. Yeah, let me break that down. 13 When did you realize the mistake in this 14 paper? 15 A. Well, there's other references 01:49 PM 16 where it cites to so -- what was the 17 question? 18 Q. Just when did you realize that 19 that statement about -- that you attribute to 20 the Pottegard paper from 2018 is patently 01:49 PM 21 inaccurate? 22 MR. NIGH: Form objection. 23 BY MR. FOWLER: 24 Q. That was gratuitous. 25 When did you realize that the 01:49 PM</p>	<p style="text-align: right;">Page 177</p> <p>1 BY MR. FOWLER: 2 Q. And in follow up to that, you 3 don't have any additional opinions with 4 regard to the issues in this case that are 5 not contained in your report? 01:51 PM 6 MR. NIGH: Form objection. 7 A. Correct. 8 BY MR. FOWLER: 9 Q. Okay. 10 A. I mean, if somebody asks me a 01:51 PM 11 question about -- you know, I think in 12 context, if there was a question related to, 13 you know, a topic in here, I could have an 14 opinion on it. 15 Q. But you believe when you wrote 01:51 PM 16 this report, you were setting forth your 17 complete opinions and all the bases for those 18 opinions with regard to the questions you 19 were attempting to answer in this case? 20 MR. NIGH: Form objection. 01:51 PM 21 A. Yes. 22 BY MR. FOWLER: 23 Q. Is there any literature, any 24 articles or studies that you are aware of, 25 that is potentially impactful on your 01:51 PM</p>

<p style="text-align: right;">Page 178</p> <p>1 opinions in this case that you did not 2 consider or include in your report? 3 A. So besides the 583 references I 4 have, there are other papers which I may have 5 read that are involved in the thought 01:52 PM 6 process, but I didn't include in the 580 7 references. 8 Q. Fair enough. 9 And did you proofread your report 10 carefully before you signed it? 01:52 PM 11 A. So it was extensive report and I 12 proofread as much as I could. When you have, 13 you know, almost 600 references, when I was 14 rereading it now, I noticed there are a 15 couple references that were mistakes. 01:52 PM 16 Q. Oh, okay. Lawyers can't help 17 themselves. I'd like to follow up on that. 18 Could you please tell me where -- which 19 references you're referring to in that 20 statement? 01:53 PM 21 A. Sure. That's where I have a 22 list -- other. 23 Q. My bad. I didn't ask you about 24 that. Can I see that and we're going to mark 25 it number 9? 01:53 PM</p>	<p style="text-align: right;">Page 180</p> <p>1 we responded back. 2 MR. FOWLER: And did -- did you 3 include all defendants? I mean, I -- 4 MS. BOGDAN: Yes, it was served to 5 everyone that was on the initial Dropbox 01:54 PM 6 list. 7 MR. FOWLER: Okay. I totally 8 accept that. I just represent I haven't 9 seen this before, that's all. 10 BY MR. FOWLER: 01:54 PM 11 Q. When did you realize you had these 12 corrections that needed to be made to your 13 report? 14 A. Just very recently, when I was 15 checking my N note for a couple of paragraphs 01:54 PM 16 just got screwed up, and so there were just a 17 couple of papers that it put the wrong number 18 on, in the last couple days. 19 Q. Okay. 20 MR. FOWLER: Yeah, we'll just put 01:55 PM 21 it with the stack of exhibits. I'm not 22 going to take time to go into it. 23 BY MR. FOWLER: 24 Q. Doctor, in the course of forming 25 your opinions in this case, did there come a 01:55 PM</p>
<p style="text-align: right;">Page 179</p> <p>1 THE REPORTER: 8. 2 MR. FOWLER: 8. 3 (Exhibit 8, Virtual exhibit, marked for 4 identification.) 5 MR. NIGH: For the record, my 01:53 PM 6 understanding is this was emailed, 7 provided via email to defense counsel. 8 MR. FOWLER: And when do you think 9 that happened, because I certainly 10 haven't seen it? 01:53 PM 11 MS. BOGDAN: It was put in the 12 Dropbox and it was referenced that it 13 was in the Dropbox. 14 MR. FOWLER: Right. My question 15 was when. 01:53 PM 16 MS. BOGDAN: Two days ago. 17 MR. HARKINS: With everything 18 else. 19 MR. FOWLER: With everything else? 20 MS. BOGDAN: Yeah, with -- with -- 01:53 PM 21 MR. FOWLER: The other 400 22 articles and invoices and everything? 23 MS. BOGDAN: No, no, no, no. When 24 we had gotten a couple emails asking for 25 a specific articles yesterday, and when 01:53 PM</p>	<p style="text-align: right;">Page 181</p> <p>1 time at all when you needed -- let me start 2 that question again. 3 In the course of preparing your 4 report in this case, did you have occasion to 5 request any documents from the plaintiffs, 01:55 PM 6 that you didn't have? 7 A. I relied -- no, I relied on my own 8 peer-reviewed literature for the research. 9 Q. Yes, sir, but I think we 10 established that you were provided some 01:56 PM 11 company documents with regard to the testing? 12 A. Right, the levels of NDMA. 13 Q. Yeah. And am I also correct that 14 those documents that you were provided are 15 not included in what was marked footnote 3, 01:56 PM 16 the document production we got from 17 plaintiffs on September 7th? 18 A. I thought they were provided -- 19 Q. Do you still have the company -- 20 various company documents that you reviewed 01:56 PM 21 and relied upon? Do you still have those in 22 your possession at your office? 23 A. Yeah, I should have them. 24 Q. Right. I will double-check. I 25 represent I didn't see them on the thumb 01:57 PM</p>

<p style="text-align: right;">Page 182</p> <p>1 drive, and I would just request a copy of 2 everything that you've received and reviewed 3 in connection with your opinions. 4 Now, Doctor, you mentioned a few 5 times the number of references in your 01:57 PM 6 report. And in going through them, I would 7 represent that there were 118 of those 8 articles predated 1975. 9 Do you have any reason to dispute 10 that? 01:57 PM 11 A. That -- much of the NDMA and NDEA 12 literature was in the early '60s, '70s. The 13 first paper was 1956. 14 Q. Right. And even before 1980, the 15 175 articles that you cited, and about 230 01:58 PM 16 before the Peto study. Do you except that 17 representation approximately? 18 A. Yes. 19 MR. NIGH: Form objection. 20 BY MR. FOWLER: 01:58 PM 21 Q. Fair enough. 22 Doctor, the reason for that 23 question is this. Do you agree that the 24 studies predating Peto in 1991 that you 25 reviewed and relied upon in this case, only 01:58 PM</p>	<p style="text-align: right;">Page 184</p> <p>1 None of the animal studies that 2 you relied upon in your report reflect any 3 conclusion about the risk of carcinogenicity 4 in humans? 5 MR. NIGH: Form objection. 01:59 PM 6 A. No. The early papers in the 7 1970s, even -- there are some nature 8 publications, Montesano, Terracini 1967, 9 Terracini 1964. They'll comment on 10 implications that this could have in humans. 02:00 PM 11 So in their discussion, they may 12 talk about it or add, you know, some 13 sentences. 14 BY MR. FOWLER: 15 Q. Do you agree that all of the 02:00 PM 16 animal studies cited in your report studied 17 doses of or exposure to NDMA or NDEA higher 18 than the levels of NDMA or NDEA in the 19 valsartan tablets? 20 MR. NIGH: Form objection. 02:00 PM 21 A. No. The -- first of all, this is 22 a genotoxic carcinogen, and I agree with the 23 WHO 2002 and other agencies that it's 24 inappropriate to convert the surface area to 25 body weight from an animal to a human when 02:01 PM</p>
<p style="text-align: right;">Page 183</p> <p>1 address various mechanisms of the 2 carcinogenicity of NDMA or NDEA in the animal 3 studies that you looked at? 4 MR. NIGH: Form objection. 5 BY MR. FOWLER: 01:58 PM 6 Q. Do you follow my question, sir? 7 A. I'm not sure I understand the 8 question. 9 Q. Do all of the animal studies that 10 predate Peto, 1991, are all of those only 01:59 PM 11 about the mechanism of the NDMA 12 carcinogenicity and NDEA carcinogenicity in 13 animals? 14 MR. NIGH: Form objection. 15 A. No, there are some papers that are 01:59 PM 16 about -- they give the carcinogen NDMA and 17 they look at the readout which is cancer. 18 BY MR. FOWLER: 19 Q. Yes, sir. 20 A. So some of the papers are -- some 01:59 PM 21 papers look into mechanisms, but others 22 don't. 23 Q. Can we agree that none of the 24 animal studies that you look at are -- let me 25 start that again. 01:59 PM</p>	<p style="text-align: right;">Page 185</p> <p>1 you're talking about a genotoxic mutagenic 2 carcinogen such as NDMA and NDEA, where the 3 mechanism of action of the metabolism is 4 virtually identical in animals and humans. 5 So a genotoxic carcinogen, there's 02:01 PM 6 no safe dose. So even a molecule could cause 7 cancer. So most of the advice has been to 8 minimize exposure. 9 BY MR. FOWLER: 10 Q. Yes, sir. My question was a 02:01 PM 11 little different. Let me try it again. 12 All of the animal studies that you 13 rely upon involve doses of NDMA or NDEA 14 greater than the levels that were measured in 15 the affected valsartan tablets. Can we agree 02:02 PM 16 on that? 17 MR. NIGH: Form objection. 18 A. I'd have to look at the study and 19 look at the exact comparison between a 20 particular study and a particular tablet. 02:02 PM 21 So -- but, like I said, when I get back 22 to it, it's a genotoxic carcinogen where we 23 don't extrapolate from the dose in the animal 24 to the dose in the human. There's no safe 25 dose. There's no threshold here. 02:02 PM</p>

<p style="text-align: right;">Page 186</p> <p>1 This is -- whenever -- and this is</p> <p>2 also -- this is -- NDMA and NDEA are used to</p> <p>3 initiate cancer in the lab. In fact, one</p> <p>4 single dose of NDMA can cause cancer in about</p> <p>5 20 subspecies of mice, you know, 10 02:03 PM</p> <p>6 subspecies of rats in fish and hamsters, and</p> <p>7 a single dose of NDEA can cause cancer in</p> <p>8 about 60 substrains of mice, 20 substrains of</p> <p>9 rats, fish, hamsters.</p> <p>10 And this is a carcinogen that's 02:03 PM</p> <p>11 used to initiate cancer worldwide in about</p> <p>12 six different types of cancers with NDEA and</p> <p>13 another five or six different types of cancer</p> <p>14 in NDMA, so this is a carcinogen that</p> <p>15 people -- and also, just to quote the EPA, 02:03 PM</p> <p>16 why it's a likely carcinogen, is that the</p> <p>17 route of administration in animals, whether</p> <p>18 it's oral inhalation, subQ or IP or IM can</p> <p>19 cause cancer, so...</p> <p>20 BY MR. FOWLER: 02:04 PM</p> <p>21 Q. Did you lose the question, Doctor?</p> <p>22 A. I'm sorry, what's the question?</p> <p>23 Q. Did you lose the question in your</p> <p>24 answer?</p> <p>25 A. Well, I'm trying to explain why 02:04 PM</p>	<p style="text-align: right;">Page 188</p> <p>1 Doctor, a single dose of a certain amount,</p> <p>2 which is typically measured in like</p> <p>3 milligrams per kilogram, correct?</p> <p>4 A. Correct.</p> <p>5 MR. NIGH: Form objection. 02:05 PM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. When you say a single dose, you're</p> <p>8 not trying to suggest it was, like, one</p> <p>9 molecule, it was a dose but the amount of</p> <p>10 that dose was -- was significant? Was a high 02:05 PM</p> <p>11 dose that was given?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. What's important here is that this</p> <p>14 is a genotoxic mutagen, so even a molecule</p> <p>15 can interact with the DNA of a target cell. 02:05 PM</p> <p>16 So that's why with genotoxic carcinogens</p> <p>17 we're very careful as a field to extrapolate</p> <p>18 with a dose response. So there's no</p> <p>19 threshold with genotoxic mutagenic</p> <p>20 carcinogens. 02:06 PM</p> <p>21 And what I was trying to make the</p> <p>22 point that this is a carcinogen NDMA and NDEA</p> <p>23 that are used to initiate cancer. So they're</p> <p>24 very potent carcinogens. And what the EPA --</p> <p>25 what we look at it's multiple species. So an 02:06 PM</p>
<p style="text-align: right;">Page 187</p> <p>1 converting a dose from an animal to a human</p> <p>2 is not relevant in this case.</p> <p>3 Q. The single-dose studies that</p> <p>4 you're referring to in all those species,</p> <p>5 that dose was a near-lethal dose to those 02:04 PM</p> <p>6 animals, right? It wasn't one molecule,</p> <p>7 right?</p> <p>8 MR. NIGH: Form objection.</p> <p>9 BY MR. FOWLER:</p> <p>10 Q. Let me start that again. 02:04 PM</p> <p>11 The single-dose studies, the</p> <p>12 animals were administered a dose far greater</p> <p>13 than the levels of NDMA in the valsartan,</p> <p>14 weren't they, Doctor?</p> <p>15 MR. NIGH: Form objection. 02:04 PM</p> <p>16 A. So they weren't a lethal dose. To</p> <p>17 get cancer, the animals have to go a certain</p> <p>18 period. So there wasn't a toxic dose where</p> <p>19 they suddenly died in 24 hours. A single</p> <p>20 dose of NDEA, for example, a single dose can 02:05 PM</p> <p>21 cause liver cancer, for example, a couple</p> <p>22 weeks later. And so that's not a -- you</p> <p>23 asked about a toxic dose.</p> <p>24 BY MR. FOWLER:</p> <p>25 Q. When you say a single dose, 02:05 PM</p>	<p style="text-align: right;">Page 189</p> <p>1 NDEA can cause cancer in 18 different</p> <p>2 species. You know, NDMA causes cancer in at</p> <p>3 least 10 different species. And then it's</p> <p>4 multiple sites, so multiple tumor types. And</p> <p>5 by different -- about six different ways of 02:06 PM</p> <p>6 administration.</p> <p>7 BY MR. FOWLER:</p> <p>8 Q. Doctor, when you yourself in your</p> <p>9 laboratory use NDMA or NDEA to induce tumors,</p> <p>10 you were administering a dose hundreds, 02:07 PM</p> <p>11 hundreds of times higher than the level of</p> <p>12 NDMA or NDEA in the valsartan tablets; isn't</p> <p>13 that true?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. So the dose we give in the 02:07 PM</p> <p>16 animals, for example, it makes per kg is --</p> <p>17 so that -- I would have to see the comparison</p> <p>18 that you're talking about with the particular</p> <p>19 tablet.</p> <p>20 BY MR. FOWLER: 02:07 PM</p> <p>21 Q. Doctor, I could put 50 animal</p> <p>22 studies in front of you with doses ranging</p> <p>23 from 10 mgs per kg up to 200 mgs per kg, you</p> <p>24 would agree that anything in that range is</p> <p>25 hundreds of times higher than the level of 02:08 PM</p>

<p style="text-align: right;">Page 190</p> <p>1 exposure at issue in the valsartan</p> <p>2 litigation, right?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. So in general --</p> <p>5 BY MR. FOWLER: 02:08 PM</p> <p>6 Q. Can we answer that and then</p> <p>7 explain?</p> <p>8 A. Okay. Yes.</p> <p>9 So, in general, there are times</p> <p>10 where a dose in the animal can be higher than 02:08 PM</p> <p>11 in a human, but in this case, because the</p> <p>12 mechanism of action of the cancer causation</p> <p>13 is virtually identical in the animals and the</p> <p>14 human, which is why the 2002 WHO said it's</p> <p>15 inappropriate to do any type of conversion 02:08 PM</p> <p>16 between the dose in an animal and the dose in</p> <p>17 a human, because this is such a potent</p> <p>18 carcinogen that's genotoxic, mutagenic,</p> <p>19 teratogenic, clastogenic, and then what's</p> <p>20 very important is that the mechanism of the 02:08 PM</p> <p>21 metabolism and action of the cancer causation</p> <p>22 is virtually identical in animals and humans.</p> <p>23 Q. We'll talk about that later. But</p> <p>24 at this moment, Doctor, can we agree that the</p> <p>25 DNA repair capacity of a human is far greater 02:09 PM</p>	<p style="text-align: right;">Page 192</p> <p>1 data. And what I get into, as a totality,</p> <p>2 that the amount that NDMA and NDEA can cause</p> <p>3 human cancer, when we take all this evidence</p> <p>4 together.</p> <p>5 BY MR. FOWLER: 02:10 PM</p> <p>6 Q. You just said and what I got into</p> <p>7 is the "totality, that the amount that NDMA</p> <p>8 and NDEA can cause cancer when we take all</p> <p>9 this together."</p> <p>10 A. Well, I'm not understanding the 02:11 PM</p> <p>11 question.</p> <p>12 Q. I'm not understanding the answer,</p> <p>13 so let's try it again.</p> <p>14 Can you point to me anywhere in</p> <p>15 your report where you evaluated the level of 02:11 PM</p> <p>16 NDMA in the valsartan tablets as an</p> <p>17 incremental increase against the other</p> <p>18 sources of NDMA and NDEA in our daily diets</p> <p>19 and that which is produced endogenously? Did</p> <p>20 you ever make that analysis? 02:11 PM</p> <p>21 A. So I. --</p> <p>22 MR. NIGH: Form objection.</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. Please start with a "yes" or "no"</p> <p>25 and then explain. 02:11 PM</p>
<p style="text-align: right;">Page 191</p> <p>1 than any DNA repair capacity in the animals</p> <p>2 that you're talking about? Can we agree on</p> <p>3 that?</p> <p>4 MR. NIGH: Form objection.</p> <p>5 A. Sure. Yes. 02:09 PM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. That's undisputed, right?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Now, Doctor, nowhere in</p> <p>10 your report do you address the question of 02:09 PM</p> <p>11 whether the incremental additional exogenous</p> <p>12 NDMA that was found in the affected valsartan</p> <p>13 tablets can cause cancer, correct?</p> <p>14 A. I don't understand the question.</p> <p>15 Q. Did you, in your -- forming your 02:09 PM</p> <p>16 opinions in your report, did you ever address</p> <p>17 the question whether the incremental increase</p> <p>18 in exogenous exposure to NDMA that is</p> <p>19 measured in the valsartan tablets, whether</p> <p>20 that amount itself can cause cancer? 02:10 PM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A. So in the 200 pages I show -- we</p> <p>23 do four lines of evidence. We have the</p> <p>24 animal studies. We have the human studies,</p> <p>25 the mouse mechanism studies, and the epi 02:10 PM</p>	<p style="text-align: right;">Page 193</p> <p>1 MR. NIGH: No, he doesn't have to</p> <p>2 start with a "yes" or "no."</p> <p>3 MR. FOWLER: The question calls</p> <p>4 for a "yes" or "no."</p> <p>5 MR. NIGH: It does not. 02:11 PM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. Did you do the analysis?</p> <p>8 A. I did consider endogenous NDMA,</p> <p>9 but endogenous NDMA, there are no reliable</p> <p>10 tests and methods to quantify it. NDMA is 02:11 PM</p> <p>11 metabolized very quickly, within minutes, and</p> <p>12 we know -- we can't do studies in humans</p> <p>13 because it's a human carcinogen, so we rely</p> <p>14 on animal experiments.</p> <p>15 So because it's metabolized very 02:12 PM</p> <p>16 quickly within eight minutes in rodent</p> <p>17 models, within 21 minutes in monkeys, there</p> <p>18 are no accurate ways to measure the</p> <p>19 endogenous NDMA's. The mechanism of action is</p> <p>20 that these DNA adducts, which are formed from 02:12 PM</p> <p>21 the cytochrome P450 enzymes attacking the</p> <p>22 NDMA and forming these methyl diazonium ions.</p> <p>23 What's important is these ions are formed</p> <p>24 very quickly at the site of action. So it</p> <p>25 is -- there's no reliable test to measure 02:12 PM</p>

<p style="text-align: right;">Page 194</p> <p>1 endogenous NDMA.</p> <p>2 And so the regulatory agencies I</p> <p>3 go with -- this is what they've all also</p> <p>4 said. So the question I was asked, does</p> <p>5 exogenous NDMA that's in a valsartan pill 02:13 PM</p> <p>6 cause human cancer? So that exogenous</p> <p>7 external NDMA, what I go through in my</p> <p>8 report, first with the animal studies and</p> <p>9 then with the FDA guidelines of 96 nanogram</p> <p>10 per day, I calculated the amount of NDMA that 02:13 PM</p> <p>11 was in the valsartan pills and compared that</p> <p>12 to the FDA allowed level of 96 nanogram per</p> <p>13 day.</p> <p>14 Q. So the basis for your opinion that</p> <p>15 the levels detected in the affected valsartan 02:13 PM</p> <p>16 tablets, the opinion that that level causes</p> <p>17 an increased risk of cancer is based upon the</p> <p>18 FDA's 96 nanogram acceptable intake, that's</p> <p>19 what you're comparing the levels measured</p> <p>20 against? 02:13 PM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A. To say something causes cancer, in</p> <p>23 the chemical -- what I've spent 30 years</p> <p>24 studying chemical carcinogenesis, the</p> <p>25 standard assay first we use is called a 02:14 PM</p>	<p style="text-align: right;">Page 196</p> <p>1 working group meetings in that year and there</p> <p>2 was no common consensus on how to describe</p> <p>3 the mechanisms of action of carcinogens and</p> <p>4 they came up -- originally they were 24</p> <p>5 characteristics and they narrowed it down to 02:15 PM</p> <p>6 10 key characteristics of carcinogens. And</p> <p>7 this IARC, and I agree with IARC, they</p> <p>8 emphasize this very highly, that in the case</p> <p>9 where there's limited human experience with,</p> <p>10 in this case, pure NDMA, NDEA, it would be 02:15 PM</p> <p>11 unethical to do any kind of experiments or</p> <p>12 trials on, then we rely on the key</p> <p>13 characteristics, and that's where I have</p> <p>14 to -- part of my report -- I not only go into</p> <p>15 the animal -- carcinogenesis assays where 02:16 PM</p> <p>16 NDMA and NDEA cause cancer in the rodents, as</p> <p>17 I said, multisite, multispecies, but then</p> <p>18 nine of the 10 key characteristics, NDMA and</p> <p>19 NDEA exhibit. So that -- and then I used</p> <p>20 human epi studies to come to my opinion. 02:16 PM</p> <p>21 BY MR. FOWLER:</p> <p>22 Q. Doctor, the 10 hallmarks you're</p> <p>23 speaking of and the IARC process is only to</p> <p>24 identify hazards; it's a hazard analysis;</p> <p>25 it's not a risk analysis, correct? 02:16 PM</p>
<p style="text-align: right;">Page 195</p> <p>1 chemical carcinogenesis assay. The standard</p> <p>2 bioassay we give to animals, the chemical.</p> <p>3 That's the first step to see does a chemical</p> <p>4 cause cancer. Most human carcinogens</p> <p>5 actually were shown to cause cancer in 02:14 PM</p> <p>6 animals first. Once a chemical causes cancer</p> <p>7 in animals, we have 60 years and hundreds of</p> <p>8 papers showing that it's a presumed human</p> <p>9 carcinogen until proven otherwise.</p> <p>10 So that's where I don't rely only 02:14 PM</p> <p>11 on animal cancer studies. Then what IARC and</p> <p>12 other institutions use, then they use human</p> <p>13 relevant mechanism studies, with human tissue</p> <p>14 and cells, then I rely on animal mechanisms</p> <p>15 and then I do human epi. 02:14 PM</p> <p>16 Since 2012, IARC has shifted focus</p> <p>17 now to these 10 key characteristics, that</p> <p>18 when there's limited human experience with a</p> <p>19 chemical, which in NDMA and NDEA, because</p> <p>20 it's so toxic, there was poisonings where 02:15 PM</p> <p>21 people died, and it's a human carcinogen, we</p> <p>22 don't have as much human evidence as some of</p> <p>23 the other carcinogens, such as radiation,</p> <p>24 arsenic and vinyl chloride.</p> <p>25 So since 2012, IARC had two 02:15 PM</p>	<p style="text-align: right;">Page 197</p> <p>1 MR. NIGH: Objection, form.</p> <p>2 A. A key process in -- yes. IARC,</p> <p>3 the goal is to identify agents that cause</p> <p>4 cancer.</p> <p>5 BY MR. FOWLER: 02:17 PM</p> <p>6 Q. Which are hazards?</p> <p>7 A. Right.</p> <p>8 Q. Perfect. Thank you.</p> <p>9 Doctor, and the 10 characteristics</p> <p>10 that you talk about, and you go on at length 02:17 PM</p> <p>11 for both compounds, those are hazard</p> <p>12 identifications, those are not risk</p> <p>13 assessments, correct?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. So I was asked does NDMA or NDEA 02:17 PM</p> <p>16 cause cancer. So the first question I go</p> <p>17 into is it -- with the IARC, is it a hazard,</p> <p>18 is this a chemical that causes cancer?</p> <p>19 That's the first step.</p> <p>20 BY MR. FOWLER: 02:17 PM</p> <p>21 Q. Yes, Doctor, in 2020 -- or 2019</p> <p>22 when you began this research, it was well</p> <p>23 established that NDMA can cause cancer in</p> <p>24 animals, and the mechanism was well</p> <p>25 established. All of those things that you 02:17 PM</p>

<p style="text-align: right;">Page 198</p> <p>1 list from the 10 hallmarks of cancer, all of 2 that was already known about NDMA and NDEA in 3 animals, correct? 4 MR. NIGH: Form objection. 5 A. Not just animals, human tissue. 02:18 PM 6 So that's why IARC back in 1978 had called 7 NDMA and NDEA "probable human carcinogens," 8 which EPA also said probable human 9 carcinogens. And NTP and the DHS, Department 10 of Health Human Services, said reasonably 02:18 PM 11 anticipate to be a human carcinogen, and 12 Health Canada and EMA also agreed with this. 13 BY MR. FOWLER: 14 Q. And you referred to these agencies 15 multiple times already today, and you think 02:18 PM 16 of them as authoritative agencies, right, EPA 17 and WHO, right? IARC? 18 A. Correct. 19 Q. And each of these agencies, as you 20 have just said, classifies NDMA and NDEA as 02:18 PM 21 only a probable carcinogen, correct? 22 MR. NIGH: Form objection. 23 BY MR. FOWLER: 24 Q. Correct? 25 A. At the time when they made that 02:19 PM</p>	<p style="text-align: right;">Page 200</p> <p>1 carcinogens are so potent and cause cancers 2 in 18, 20 different species with 10 different 3 tumor types, with six different types of 4 absorbents and now combine that with now, 5 when I looked at the key characteristics and 02:20 PM 6 NDMA and NDEA have nine of the 10 key 7 characteristics, and then I add the epi 8 studies such as Hidajat, my opinion is that 9 NDMA and NDEA are human carcinogens. 10 BY MR. FOWLER: 02:20 PM 11 Q. I definitely understood that as 12 your opinion, Doctor. 13 But what I was trying to get to 14 is, all of that same information is available 15 to IARC, to WHO, all of those agencies you 02:21 PM 16 referred to, but notwithstanding that, none 17 of them have changed their classification of 18 NDMA or NDEA, off of the two-way category 19 that it's in, correct? 20 A. Well, the Hidajat study -- 02:21 PM 21 correct, they haven't -- but they haven't 22 assessed -- as far as I know, IARC hasn't 23 reassessed NDMA since 2002. 24 Q. Okay. 25 A. So part of science, as we talked 02:21 PM</p>
<p style="text-align: right;">Page 199</p> <p>1 classification, yes. 2 Q. And today? And today? 3 MR. NIGH: Form objection. 4 A. IARC, as far as I know, hasn't 5 reviewed NDMA and NDEA since 2002. 02:19 PM 6 BY MR. FOWLER: 7 Q. Yes, sir. So each of these 8 agencies, sitting here today, classified as a 9 probable human carcinogen, and you disagree 10 with every one of these authoritative agents 02:19 PM 11 because you believe that it is a human 12 carcinogen? 13 MR. NIGH: Form objection. 14 A. Well, I also have evidence now, 15 what I put in my report on the human epi 02:19 PM 16 studies, and we get into Hidajat and the diet 17 studies. 18 And so when I look at the evidence 19 and I see that this is -- NDMA and NDEA are 20 chemicals that cause cancer through these DNA 02:20 PM 21 adducts and the mechanism of action is so 22 identical to animals where every species, 23 NDMA and NDEA, have caused cancer. We're 24 talking about over 20 species. So NDEA, like 25 I said, is 18 species. So because these 02:20 PM</p>	<p style="text-align: right;">Page 201</p> <p>1 about, we get new information, new studies, 2 they didn't have Hidajat to consider. 3 And also, like I said, there's 4 been a shift for the last eight years, from 5 2012 to 2020, these key characteristics just 02:21 PM 6 came up in the last eight years, was 7 published in 2016 and so this is a unifying 8 way to look at mechanisms of carcinogens. 9 And when they studied that, they looked at 10 about 50, 60 Group 1 carcinogens and studied 02:22 PM 11 the mechanisms that these carcinogens caused 12 cancer and they came up with these 10 13 characteristics. And each carcinogen on 14 average may have three or four key 15 characteristics, and when I did this 02:22 PM 16 research, I found that NDMA and NDEA 17 exhibited nine out of 10 key characteristics. 18 So if IARC was going to reassess 19 NDMA and NDEA, that would be a question 20 whether they would upgrade it to a Group 1 02:22 PM 21 carcinogen. 22 Q. Doctor, none of those 10 hallmarks 23 of the mechanisms or whatever those 24 characteristics are, none of those addressed 25 the question of dose and duration with regard 02:22 PM</p>

<p style="text-align: right;">Page 202</p> <p>1 to NDMA, do they?</p> <p>2 MR. NIGH: Form objection.</p> <p>3 A. No. Absolutely they're very</p> <p>4 relevant to --</p> <p>5 BY MR. FOWLER: 02:23 PM</p> <p>6 Q. I didn't --</p> <p>7 MR. NIGH: Hold on. Don't</p> <p>8 interrupt him.</p> <p>9 MR. FOWLER: I -- easy. I caught</p> <p>10 myself. Go ahead. 02:23 PM</p> <p>11 MR. NIGH: You're good.</p> <p>12 A. Maybe I do not totally understand</p> <p>13 the question.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. I'll strike the question and move 02:23 PM</p> <p>16 on.</p> <p>17 MR. FOWLER: Let's mark Exhibit 9,</p> <p>18 I hope.</p> <p>19 (Exhibit 9, Current criteria to establish</p> <p>20 human carcinogens, marked for 02:23 PM</p> <p>21 identification.)</p> <p>22 BY MR. FOWLER:</p> <p>23 Q. Doctor, before we look at 9,</p> <p>24 you've said over and over again about the</p> <p>25 similarities with animals that have been 02:23 PM</p>	<p style="text-align: right;">Page 204</p> <p>1 Q. Okay. Okay, sir.</p> <p>2 And you said a moment ago that one</p> <p>3 of the -- one part of the analysis is looking</p> <p>4 for carcinogenicity in animals for chemicals</p> <p>5 that may not be tested on humans, and you -- 02:25 PM</p> <p>6 in those situations you rely on the animal</p> <p>7 data in forming opinions, correct?</p> <p>8 A. I'm not sure --</p> <p>9 Q. Yeah, it was a terrible question.</p> <p>10 Looking at Exhibit 9, Doctor, this 02:25 PM</p> <p>11 is by Dr. Cogliano, 2004, "Current Criteria</p> <p>12 to Establish Human Carcinogens."</p> <p>13 This is something that you</p> <p>14 reference, Footnote 37, on page 21 in your</p> <p>15 report. 02:25 PM</p> <p>16 So you're familiar with this</p> <p>17 article, correct, sir?</p> <p>18 A. Yes.</p> <p>19 Q. And you look there on the first</p> <p>20 page, the enumerated paragraph 2, IARC's 02:25 PM</p> <p>21 process for carcinogen identification and</p> <p>22 evaluation; yes?</p> <p>23 A. Yes, Figure 1.</p> <p>24 Q. Paragraph 2, I'm on the first</p> <p>25 page, sir. 02:26 PM</p>
<p style="text-align: right;">Page 203</p> <p>1 studied.</p> <p>2 Let me ask you this question, sir:</p> <p>3 What is the difference between qualitative</p> <p>4 and quantitative, when we're talking about</p> <p>5 describing animal responses to NDMA? 02:24 PM</p> <p>6 A. So qualitative would be if there's</p> <p>7 certain, for example, DNA adducts,</p> <p>8 7-methylguanine or 0-6-methylguanine, if</p> <p>9 those adducts are both increased in both</p> <p>10 animals versus humans. Well, quantification 02:24 PM</p> <p>11 would try to measure the amounts and quantify</p> <p>12 it.</p> <p>13 Q. And so the qualitative</p> <p>14 similarities between rats that are studied</p> <p>15 and humans only speaks to the mechanism but 02:24 PM</p> <p>16 not the dose response in humans, correct?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 A. As I said before --</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. Is that correct, and then -- 02:24 PM</p> <p>21 A. Correct.</p> <p>22 Q. Okay.</p> <p>23 A. However, this is a genotoxic</p> <p>24 carcinogen where there's no threshold. So,</p> <p>25 like I said, before, there's no safe dose. 02:24 PM</p>	<p style="text-align: right;">Page 205</p> <p>1 A. Yes.</p> <p>2 Q. The first sentence, "The IARC</p> <p>3 monographs are an international expert</p> <p>4 consensus approach of carcinogen hazard</p> <p>5 identification," correct? 02:26 PM</p> <p>6 A. Correct.</p> <p>7 Q. And you don't disagree with that?</p> <p>8 A. Correct.</p> <p>9 Q. IARC does not assess or make</p> <p>10 statements as to the risk to humans from any 02:26 PM</p> <p>11 of the carcinogens that they identify, do</p> <p>12 they?</p> <p>13 MR. NIGH: Form objection.</p> <p>14 A. So -- yes, regulatory agencies</p> <p>15 such as FDA will come up with a certain 02:26 PM</p> <p>16 recommendation based on what IARC says.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. Yes, sir. And are you aware,</p> <p>19 Doctor, that there are instances where</p> <p>20 animals studies have produced carcinogenic 02:26 PM</p> <p>21 results that have never materialized in</p> <p>22 humans, for the same chemical?</p> <p>23 A. So --</p> <p>24 Q. Are you aware?</p> <p>25 A. -- yes. For example, I can give 02:26 PM</p>

<p style="text-align: right;">Page 206</p> <p>1 you an example of saccharin where -- you want 2 me -- 3 Q. That's where I'm going, sir. 4 So page 410 of this article, sir. 5 You see at the top of the second column the 02:27 PM 6 example? This is under the example of 7 "Evaluations changed by mechanistic data." 8 The example is saccharine. "NTP does not 9 list saccharine on its report of carcinogens 10 because the observed urinary bladder cancers 02:27 PM 11 in rats are related to the physiology, it 12 goes on the urinary pH." 13 The concluding sentence says "The 14 factors thought to contribute to tumor 15 induction by sodium saccharine in rats would 02:27 PM 16 not be expected to occur in humans." 17 Do you see that? 18 A. Yes. 19 Q. And since we're the same age, you 20 remember like when all the Sweet & Low jumped 02:27 PM 21 off the shelf and everybody thought 22 saccharine would be carcinogenic? 23 A. Right. 24 Q. And that turned out not to be 25 true? 02:27 PM</p>	<p style="text-align: right;">Page 208</p> <p>1 Q. Yes, sir. Now let's look on that 2 same page, the bottom of the first column, 3 another example. It states, "NTP does not 4 list ethyl acrylate in its report on 5 carcinogens because one, the four stomach 02:29 PM 6 tumors induced in animal studies were only 7 seen when ethyl acrylate was administered by 8 gavage at high concentrations that induced 9 market lower irritation and cellular 10 proliferation. Two, animal studies by other 02:29 PM 11 routes of administration, including 12 inhalation were negative. And three, because 13 significant chronic human oral exposure to 14 high concentrations of ethyl acrylate the 15 monomer is unlikely." 02:29 PM 16 Do you see where I read there? 17 A. Yes. 18 Q. And the reason they didn't -- the 19 NTP didn't include it on the list, because 20 humans are unlikely to encounter the high 02:30 PM 21 concentration of that chemical that was 22 administered to animals in order to elicit 23 carcinogenicity. Isn't that what they're 24 saying? 25 MR. NIGH: Form objection. 02:30 PM</p>
<p style="text-align: right;">Page 207</p> <p>1 A. Right. So the story -- this is 2 actually a very -- 3 Q. Do I have to hear it now? Do we 4 have an ear later? 5 A. Later. 02:28 PM 6 Q. Okay. 7 A. But I will say that saccharin 8 initially IARC put it on their list of 9 carcinogens. And, like I said, when a 10 chemical causes cancer, it's a presumed human 02:28 PM 11 carcinogen until proven otherwise. This is 12 one of the few examples where after all the 13 epi data came out, it was shown to be safe. 14 And then what was key in that case is that it 15 was a rat-specific mechanism. Only rats got 02:28 PM 16 the cancers. It wasn't relevant to humans. 17 So it's very different from this 18 case, NDMA and NDEA, where I cited many 19 papers showing the human relevance with human 20 tissues in seven different human tissues and 02:28 PM 21 then I cited epi evidence supporting NDMA and 22 NDEA in causing human cancer. 23 So that's why -- and then at some 24 point IARC removed saccharine from its list 25 of carcinogens. 02:29 PM</p>	<p style="text-align: right;">Page 209</p> <p>1 A. This case is very different from 2 NDMA and NDEA. We can just go step by step. 3 First one, the four stomach 4 tumors, NDMA and NDEA, like I said, cause 5 over 10 different type tumors in the animals, 02:30 PM 6 so it's not a specific to one type of tumor. 7 And the routes here including inhalation were 8 negative. NDMA, there are six routes of 9 administration that causes cancer, oral 10 inhalation, subcutaneous, intraperitoneal, 02:30 PM 11 intratracheal, intramuscular. 12 And so when a regulatory agency or 13 a scientific body, and this is what EPA has 14 said, IARC has said, whenever you see a 15 chemical that causes multiple cancer types in 02:31 PM 16 multiple sites in multiple species by 17 multiple routes of administration, that is a 18 presumed animal -- that is a presumed human 19 carcinogen until proven otherwise. 20 BY MR. FOWLER: 02:31 PM 21 Q. Yes, I've heard you say that a few 22 times. But I'm more interested in the third 23 reason here, because humans are unlikely to 24 be -- let me say it correctly. "Because 25 significant chronic human oral exposure to 02:31 PM</p>

<p style="text-align: right;">Page 210</p> <p>1 high concentrations of ethyl acrylate monomer 2 are unlikely."</p> <p>3 And Doctor, that's where I'd like 4 to focus your attention.</p> <p>5 The NDMA, from the valsartan 02:31 PM 6 tablets, is only consumed orally, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And the concentrations of NDMA 9 that were given to rodents or other animals 10 orally by gavage or otherwise, are at a 02:31 PM 11 concentration hundreds of times higher than 12 the NDMA that was detected in the valsartan 13 tablets; isn't that correct?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. So this is where I go back to what 02:32 PM 16 I said before. It's inappropriate to use 17 conversions of surface area and body weight 18 from animals to human. This has been said by 19 WHO 2002, it is highly inappropriate. 20 Because the mechanism of cancer causation in 02:32 PM 21 NDMA and NDEA is highly similar in animals 22 and humans because of the metabolism of the 23 chemical of the carcinogen. The formation of 24 these ions, the methyldiazonium ion in NDMA, 25 the ethyl diazonium in NDEA is virtually 02:32 PM</p>	<p style="text-align: right;">Page 212</p> <p>1 A. So that's correct to a certain 2 point. But if you look at the 1970 nature 3 publications. So in science, there are 4 procedures journals, which are, like, it's 5 like the Patriots winning the Super Bowl, 02:34 PM 6 making the Super Bowl. Does nature sell 7 science?</p> <p>8 So in 1970s Montesano McGee had a 9 nature publication. The reason why it was in 10 the highest journal is they compared tissues 02:34 PM 11 from rats and humans and the exact 12 metabolism, they quantified the metabolism, 13 it was .13 percent versus .17 percent, so it 14 was quantified. It wasn't just qualitative 15 that the DNA adducts go up and down, they 02:34 PM 16 quantified it. And the quantification of the 17 metabolism in the animals and the humans were 18 virtually identical. There's .13 to .17. 19 And they use exhalation of carbon dioxide, of 20 aldehydes, which is another carcinogen, that 02:34 PM 21 in both cases the quantification was done. 22 So in these kind of experiments you can 23 quantify and compare an animal experiment to 24 a human experiment. And this was in one of 25 the most prestigious scientific journals, it 02:35 PM</p>
<p style="text-align: right;">Page 211</p> <p>1 identical, and that's where this -- these 2 chemicals will initiate that process which 3 will -- these ions will cause target DNA in 4 the local tissue where this is happening, 5 where these enzymes, which are called 02:32 PM 6 cytochrome P450 enzymes are expressed, that 7 happens very quickly and that causes DNA 8 damage mutations and that's where the cancer 9 is initiated.</p> <p>10 Because that's such a very potent 02:33 PM 11 process, there's a reason why we don't use 12 conversions from animals to humans. When you 13 have a potent genotoxic mutagenic chromogenic 14 chemical, and where even there's no 15 threshold, so even any dose can cause cancer 02:33 PM 16 in this case.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. A couple follow-ups, Doctor.</p> <p>19 First of all, when you say the 20 metabolism and things like that in animals 02:33 PM 21 are identical, you're only speaking 22 qualitatively not quantitatively, correct, 23 sir?</p> <p>24 A. Actually --</p> <p>25 Q. Please. 02:33 PM</p>	<p style="text-align: right;">Page 213</p> <p>1 was a landmark publication. It really 2 established that decent class of 3 nitrosamines, especially NDMA and NDEA, are 4 cohorts of concern.</p> <p>5 And then that followed by 1980, 02:35 PM 6 with Shank study where the poisoning, 7 unfortunately, humans were poisoned actually 8 in Germany and in the U.S.</p> <p>9 The U.S. case was written up in a 10 1980 cancer research paper, and that showed 02:35 PM 11 that the exact DNA adducts that they had 12 measured in 1970, the O-6 and the N7 were 13 identified in the human liver cells from 14 these people. So that's --</p> <p>15 And also, we know from the past 02:35 PM 16 that in people, in the 1930s when they got 17 the NDMA, they died from liver toxicity with 18 acute encephalitis, with ascites, and that 19 was very important because that's what the 20 animals, when you give toxic doses of NDMA, 02:36 PM 21 can die from.</p> <p>22 So in science we don't rely on one 23 particular paper or a few papers. It's the 24 whole field in general, and that's why with 25 the 1970 publication in Nature, on NDMA and 02:36 PM</p>

<p style="text-align: right;">Page 214</p> <p>1 the 1980 publication on human patients that 2 were poisoned, a human, that's where the 3 people realized that this is a very -- it's 4 basically a poison, a dangerous chemical and 5 why we don't convert dose from an animal to a 02:36 PM 6 human. 7 Q. Doctor, first of all, in the 8 1970s, Nature was an open-access journal, 9 wasn't it? It was not a peer-reviewed 10 journal, correct? 02:36 PM 11 MR. NIGH: Form objection. 12 A. It still is a prestigious journal. 13 BY MR. FOWLER: 14 Q. It's open access, it's not peer 15 reviewed? 02:37 PM 16 MR. NIGH: Form objection. 17 A. I would have to look and see that. 18 BY MR. FOWLER: 19 Q. Right. And secondly, Doctor, 20 returning to the question that I asked, and 02:37 PM 21 I'd really like for you to please try to 22 answer this question. 23 It is unlikely that humans are 24 going to be exposed to the high concentration 25 of NDMA or NDEA that are used in the animal 02:37 PM</p>	<p style="text-align: right;">Page 216</p> <p>1 You would agree that it is highly 2 unlikely that humans are going to be exposed 3 to the high concentration of NDMA or NDEA 4 that was used in the animal studies that you 5 rely upon? 02:38 PM 6 MR. NIGH: Form objection. 7 A. So what I would agree is that in 8 general -- and then I'll talk about NDMA. 9 That in animal experiments sometimes you give 10 higher doses than people, and there's a 02:38 PM 11 reason for that; to see effects in animals -- 12 with an end of 10, an end of 20, an end of 30 13 and equal, you have to do certain doses; but 14 this doesn't apply to a genotoxic carcinogen 15 such as NDMA. 02:38 PM 16 BY MR. FOWLER: 17 Q. Okay. Doctor, you've never 18 published any research about genotoxic 19 compounds before, have you, sir? 20 MR. NIGH: Form objection. 02:39 PM 21 A. Correct. 22 BY MR. FOWLER: 23 Q. You have never researched in your 24 professional life, outside of this case, 25 genotoxic compounds like NDMA? 02:39 PM</p>
<p style="text-align: right;">Page 215</p> <p>1 studies. Yes or no, sir? 2 MR. NIGH: Hold on. I'm going to 3 object to the colloquy. I believe it's 4 inappropriate. He answered that last 5 question. Gave a specific example of 02:37 PM 6 how -- 7 MR. FOWLER: You can object, 8 Counsel, but this is not -- 9 MR. NIGH: No, no, but you keep 10 starting your questions with colloquys, 02:37 PM 11 and we've been to the Court before where 12 he says not to badger the witness with 13 nonresponsive statements. You're trying 14 to do it with a code of something else. 15 But you just did it again. So I'm going 02:37 PM 16 to put that on the record. It's very 17 clear that he answered the question 18 beforehand. You can go. When you say 19 return to the question -- 20 MR. FOWLER: The record will speak 02:37 PM 21 for itself. 22 MR. NIGH: Sure. 23 BY MR. FOWLER: 24 Q. Let me ask the question again, 25 Doctor. 02:38 PM</p>	<p style="text-align: right;">Page 217</p> <p>1 MR. NIGH: Form objection. 2 A. So independently we do use NDMA 3 and NDEA in the lab, like I said, to -- 4 BY MR. FOWLER: 5 Q. Yes, sir. 02:39 PM 6 A. -- to stimulate oxidative stress 7 to cause cancer. 8 Q. Yes, sir, but my question was have 9 you researched NDMA -- that wasn't my 10 question. 02:39 PM 11 My question was, has your research 12 involved genotoxic compounds? 13 MR. NIGH: Form objection. 14 A. We focused on nongenotoxic 15 carcinogens in our research, but I had to 02:39 PM 16 review and know about. 17 BY MR. FOWLER: 18 Q. Is that why you spent a thousand 19 hours in this case, because you've never done 20 this before in your life and so you needed to 02:39 PM 21 read up to genotoxic compounds? 22 MR. NIGH: Form objection, 23 argumentative. 24 A. The reason why I spent -- the 25 reason this case involved -- and this was a 02:40 PM</p>

<p style="text-align: right;">Page 218</p> <p>1 complex case with two carcinogens with 60 2 years of literature on each carcinogen and 3 then 10 different tumor types that I focused 4 in on and then, like I said, nine key 5 characteristics, so this was a complex case 02:40 PM 6 that involved a -- and also, just in a 7 particular lab, you develop a certain 8 expertise, but you still are familiar and you 9 have to know other concepts. So our 10 expertise, I would agree, is more 02:40 PM 11 nongenotoxic mechanisms, such as 12 inflammation, angiogenesis as a lab. I mean, 13 I trained in the lab that pioneered 14 angiogenesis, the Judah Folkman lab, and then 15 we focused on inflammation as our... 02:40 PM 16 BY MR. FOWLER: 17 Q. Yes, sir. And Doctor, before we 18 get further into it, you've said several 19 times here today that you don't believe that 20 there's a threshold with NDMA or NDEA. You 02:41 PM 21 recall those statements time and again here? 22 A. Correct. 23 Q. You also agree that there's at 24 least six or eight papers that you cite in 25 your report that actually say there is 02:41 PM</p>	<p style="text-align: right;">Page 220</p> <p>1 You agree that there is some level 2 of endogenous production of NDMA and NDEA in 3 the body? We're not talking about how much, 4 we may disagree. My question to you, clean 5 question, do you agree that there is a level 02:42 PM 6 of endogenous production of NDMA and NDEA in 7 the body? 8 MR. NIGH: Form objection. 9 A. So Spiegelhalter looked at that 10 exact question and there's some -- so in 02:42 PM 11 science we like to see the data, the 12 evidence. We can hypothesize all we want. 13 So because there's no reliable method to 14 measure the endogenous NDMA, like I mentioned 15 before, because of the quick metabolism and 02:43 PM 16 the challenges, that I haven't seen a paper 17 in vivo that reliably quantifies the amount 18 of endogenous NDMA without any exogenous 19 amount. So Spiegelhalter tried to do it with 20 human patients, and unless they added 02:43 PM 21 alcohol, the endogenous levels of NDMA in the 22 urine were not detectable. So people have 23 tried to look at it. But regulatory agencies 24 always have said there's no reliable method 25 to quantify the amount of NDMA that's 02:43 PM</p>
<p style="text-align: right;">Page 219</p> <p>1 without a doubt a threshold for NDMA and 2 NDEA? Do you recall that in the papers 3 you've cited to? 4 MR. NIGH: Form objection. 5 A. I would have to see where those 02:41 PM 6 papers -- so. 7 BY MR. FOWLER: 8 Q. Okay. That's fine. I just 9 wondered if you knew that the papers you 10 cited say that there's a threshold. And I 02:41 PM 11 just didn't -- I wanted to see that before we 12 get into it. 13 MR. NIGH: Form objection. 14 BY MR. FOWLER: 15 Q. Do you recall that or not? 02:41 PM 16 MR. NIGH: Form objection. 17 A. So nongenotoxic carcinogens 18 have -- are thought to have a threshold, and 19 genotoxic carcinogens -- regulatory agencies 20 and scientific bodies view it as there's no 02:42 PM 21 safe thresh- -- no safe dose and that any 22 exposure should be minimized. 23 BY MR. FOWLER: 24 Q. I understand. Doctor, we agree -- 25 let's start that again. 02:42 PM</p>	<p style="text-align: right;">Page 221</p> <p>1 endogenous. 2 Q. I understand -- strike that. 3 Doctor, that's a quantitative 4 question. 5 My question was not asking you for 02:44 PM 6 a level. My question is simply this, and 7 I'll break it down: Do you understand that 8 humans produce in their bodies carcinogen 9 chemicals? Let's start at that high level. 10 MR. NIGH: Hold on. Object to the 02:44 PM 11 colloquy. 12 MR. FOWLER: I started a fresh 13 question. 14 MR. NIGH: I'm going to object to 15 the colloquy that led off that question 02:44 PM 16 because he was responsive to your 17 question; and then I'll object to form. 18 BY MR. FOWLER: 19 Q. I'm going to start fresh here, 20 Doctor. 02:44 PM 21 A. Start a new question, yeah. 22 Q. Do you or do you not understand 23 that the human body produces carcinogens 24 every single day? 25 A. I want to know which carcinogens 02:44 PM</p>

<p style="text-align: right;">Page 222</p> <p>1 and --</p> <p>2 Q. Right now I'm starting at a super</p> <p>3 high level to see where we can agree. Do you</p> <p>4 agree that humans produce various carcinogens</p> <p>5 in the body every day? 02:44 PM</p> <p>6 A. I'd want to know more</p> <p>7 specifically, what are we talking about.</p> <p>8 Q. Do you believe that humans do not</p> <p>9 produce any carcinogens in the body every</p> <p>10 day? 02:45 PM</p> <p>11 MR. NIGH: Form objection.</p> <p>12 A. So I focused here on exogenous</p> <p>13 carcinogens that were in the contaminated</p> <p>14 valsartan tablet. I didn't -- there were no</p> <p>15 reliable ways to measure endogenous NDMA, so 02:45 PM</p> <p>16 I focused on exogenous cancer causation</p> <p>17 chemicals and NDMA --</p> <p>18 THE REPORTER: And what?</p> <p>19 A. Exogenous or external NDMA. So --</p> <p>20 I still don't understand the question. Is 02:45 PM</p> <p>21 there a specific carcinogen you're referring</p> <p>22 to?</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. I was trying to start with</p> <p>25 something super broad in response to your 02:45 PM</p>	<p style="text-align: right;">Page 224</p> <p>1 the ROS antibody, right?</p> <p>2 A. Yes, that's very important.</p> <p>3 Q. And, Doctor, ROS is produced by</p> <p>4 the mitochondria in the cells every day,</p> <p>5 every minute of every day, correct? 02:47 PM</p> <p>6 A. Correct.</p> <p>7 Q. And reactive oxygen species are a</p> <p>8 component of an acute inflammatory response,</p> <p>9 right?</p> <p>10 A. Yes. 02:47 PM</p> <p>11 Q. ROS is not unique to NDMA, right?</p> <p>12 A. Correct.</p> <p>13 Q. Do you have an opinion whether or</p> <p>14 not human beings produced nitrosamines in</p> <p>15 general in the body, sir? 02:47 PM</p> <p>16 A. Like I said, before, to detect</p> <p>17 endogenous NDMA is very challenging. So I</p> <p>18 would have to see a publication where there</p> <p>19 was a reliable method to quantify that.</p> <p>20 Q. Okay. And I -- let me ask my 02:48 PM</p> <p>21 question again.</p> <p>22 Do human beings produce</p> <p>23 nitrosamines, was my question, sir.</p> <p>24 A. So there may be some endogenous</p> <p>25 nitrosamine production, but it is not likely 02:48 PM</p>
<p style="text-align: right;">Page 223</p> <p>1 question.</p> <p>2 Doctor, do human beings produce</p> <p>3 formaldehyde in the body?</p> <p>4 A. So -- yes.</p> <p>5 Q. Thank you, Doctor. And 02:46 PM</p> <p>6 formaldehyde is a carcinogen, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And formaldehyde is one of the</p> <p>9 metabolites of NDMA, correct?</p> <p>10 A. Correct. 02:46 PM</p> <p>11 Q. And in your report, you rely upon</p> <p>12 the fact that formaldehyde is produced as a</p> <p>13 byproduct of NDMA metabolism, correct?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. It's a sign of the particular 02:46 PM</p> <p>16 mechanism of metabolism.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. Yes, sir. And in your report and</p> <p>19 the papers, formaldehyde is produced, and</p> <p>20 it's an equal molar. So one molar of 02:46 PM</p> <p>21 formaldehyde to one of the methylating</p> <p>22 metabolite that's produced by NDMA, right?</p> <p>23 A. Right.</p> <p>24 Q. Okay. Doctor, you also talk in</p> <p>25 your report about reactive oxygen species, 02:47 PM</p>	<p style="text-align: right;">Page 225</p> <p>1 biologically relevant. There's a couple</p> <p>2 reasons for that. If endogenous compounds</p> <p>3 cause cancer, then, for example, prostate</p> <p>4 cancer, only one in eight people get it. If</p> <p>5 you had endogenous compounds in your body 02:48 PM</p> <p>6 that were causing cancer then everybody would</p> <p>7 have cancer. So it turns out, fortunately,</p> <p>8 we have mechanisms that turn off those</p> <p>9 carcinogens, like you mentioned oxidative</p> <p>10 stress. We have -- 02:49 PM</p> <p>11 THE REPORTER: We have mechanisms</p> <p>12 that turn off that --</p> <p>13 THE WITNESS: The pro --</p> <p>14 inflammatory pro-oxidative stress</p> <p>15 mechanisms. For example, superoxide 02:49 PM</p> <p>16 dismutase is an enzyme that will turn</p> <p>17 off that oxidative stress. So</p> <p>18 fortunately in our body most of us have</p> <p>19 these defense mechanisms. We have</p> <p>20 immune cells that will turn off these 02:49 PM</p> <p>21 insults, for example.</p> <p>22 BY MR. FOWLER:</p> <p>23 Q. Did I understand you to say that</p> <p>24 it is because of the body's defense</p> <p>25 mechanisms that people do not develop cancer 02:49 PM</p>

<p style="text-align: right;">Page 226</p> <p>1 from endogenously-produced things like NDMA?</p> <p>2 MR. NIGH: Form objection.</p> <p>3 A. So there's no publication that</p> <p>4 I've seen that showed endogenous NDMA caused</p> <p>5 cancer. So what we do know is that when we 02:49 PM</p> <p>6 give -- and what's relevant in this case, is</p> <p>7 that when we give exogenous NDMA, and I'll</p> <p>8 start with animal models. Like in, for</p> <p>9 example, in the frog we give exogenous NDMA</p> <p>10 50 percent of the frogs will get cancer 02:50 PM</p> <p>11 within four to five months. None of the</p> <p>12 frogs in the control group get cancer. If</p> <p>13 endogenous NDMA was driving cancer, then</p> <p>14 endogenous NDMA would be causing cancer in</p> <p>15 that group. 02:50 PM</p> <p>16 What we study in the chemical</p> <p>17 carcinogenesis bioassay, we give the</p> <p>18 carcinogens externally, and then we look at</p> <p>19 cancer in the controlled group and then in</p> <p>20 the exposed group. And that's where we can 02:50 PM</p> <p>21 say that exogenous NDMA is what's</p> <p>22 biologically relevant and causes the cancer.</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. Doctor, I want to make sure we</p> <p>25 agree on some terminology. 02:51 PM</p>	<p style="text-align: right;">Page 228</p> <p>1 enzyme that would normally repair and be</p> <p>2 good. So that's why I mention for key</p> <p>3 characteristic number 3, which is very</p> <p>4 important. Impaired DNA repair leads to</p> <p>5 genomic instability. So one of the 02:52 PM</p> <p>6 mechanisms where NDMA can cause cancer is</p> <p>7 through -- by affecting that DNA repair</p> <p>8 process.</p> <p>9 And I have to say more -- see, we</p> <p>10 view now cancer as a holistic process. We 02:52 PM</p> <p>11 don't view as one mechanism. So carcinogens</p> <p>12 in the past decades have been referred to as</p> <p>13 "genotoxic" and "nongenotoxic." But now we</p> <p>14 know with the key characteristics, which has</p> <p>15 been over the past eight years now, that 02:53 PM</p> <p>16 these 10 key characteristics -- and just so</p> <p>17 we're clear, so the electrophilic adducts,</p> <p>18 the genotoxicity, the impaired DNA repair,</p> <p>19 the chronic inflammation, oxidative stress,</p> <p>20 immunosuppression, the apoptosis, those all 02:53 PM</p> <p>21 can attribute to cancer. So when we talk</p> <p>22 about cancer causation, we don't just focus</p> <p>23 in on one key characteristic, like an</p> <p>24 impaired DNA repair.</p> <p>25 Q. Okay. We're getting a copy 02:53 PM</p>
<p style="text-align: right;">Page 227</p> <p>1 Do you agree that "endogenous"</p> <p>2 means produced in the body without an</p> <p>3 exogenous component --</p> <p>4 A. Yes.</p> <p>5 Q. -- outside of the body? 02:51 PM</p> <p>6 MR. NIGH: Form objection.</p> <p>7 A. Yes.</p> <p>8 BY MR. FOWLER:</p> <p>9 Q. And do we agree that "exogenous"</p> <p>10 means from outside the body? 02:51 PM</p> <p>11 A. Correct.</p> <p>12 Q. And do we agree that the human DNA</p> <p>13 repair capacity is able to repair adducts</p> <p>14 caused by NDMA, regardless of the source?</p> <p>15 MR. NIGH: Form objection. 02:51 PM</p> <p>16 A. So -- I don't understand the</p> <p>17 question.</p> <p>18 BY MR. FOWLER:</p> <p>19 Q. Does the human DNA repair system</p> <p>20 repair the mutations caused by NDMA or do you 02:52 PM</p> <p>21 know?</p> <p>22 A. So in a general process, that's</p> <p>23 what MGMT and these DNA repair enzymes will</p> <p>24 repair an adduct. However, NDMA can disrupt</p> <p>25 that repair process. It can disrupt that 02:52 PM</p>	<p style="text-align: right;">Page 229</p> <p>1 together, Doctor. We're going to mark the</p> <p>2 next exhibit, Exhibit 10.</p> <p>3 While he's fixing that, let me ask</p> <p>4 you this question. Do you agree that NDMA is</p> <p>5 NDMA, regardless of whether it comes from 02:54 PM</p> <p>6 your grilled meat, from the valsartan tablet,</p> <p>7 or from smoked cod fish? Do you agree that</p> <p>8 regardless of the source, NDMA is NDMA,</p> <p>9 correct?</p> <p>10 A. Correct. 02:54 PM</p> <p>11 Q. And the toxicity, the properties</p> <p>12 of toxicity of NDMA are the same, whether</p> <p>13 that molecule came from your barbecue, from</p> <p>14 your beer, or from the affected valsartan</p> <p>15 during the relevant time, the toxicity of the 02:55 PM</p> <p>16 molecule is the same?</p> <p>17 A. Yeah, that's what I'm saying.</p> <p>18 That one molecule can -- because it is a</p> <p>19 genotoxic chemical, it can cause cancer.</p> <p>20 Q. Okay. But my question was simply, 02:55 PM</p> <p>21 the toxicity -- the properties of toxicity of</p> <p>22 NDMA are the same regardless of the source?</p> <p>23 We can agree on that, right?</p> <p>24 A. Correct.</p> <p>25 Q. The metabolism of NDMA is the same 02:55 PM</p>

<p style="text-align: right;">Page 230</p> <p>1 whether it came from your barbecue, your 2 beer, or from the valsartan tablet, correct? 3 A. Correct. 4 MR. NIGH: Form objection. 5 BY MR. FOWLER: 02:55 PM 6 Q. The same enzyme metabolizes NDMA, 7 whether -- regardless of the source, correct? 8 MR. NIGH: Form objection. 9 A. Yes, in general there are certain 10 enzymes that can repair the O-6 and O-7 02:56 PM 11 methyl adducts, MGMT. But I would have to 12 see, if you're getting into more specific 13 examples, you know, I would have to see the 14 specifics. 15 BY MR. FOWLER: 02:56 PM 16 Q. Yep, I didn't ask about the 17 repair. I asked about the metabolism. That 18 the same enzyme metabolizes NDMA regardless 19 of its source? 20 A. Yes. 02:56 PM 21 MR. FOWLER: Now we're marking 10. 22 (Exhibit 10, Intragastric formation and 23 modulation of N-nitrosodimethylamine in a 24 dynamic in vitro gastrointestinal model under 25 human physiological conditions, marked for 02:56 PM</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. Okay. Thank you. 2 A. Yeah, 2.3 to 432 [sic] microgram. 3 Q. Thank you. 4 You'd agree that's what they 5 found -- 02:58 PM 6 A. Yeah. 7 Q. -- in the gastric model that they 8 created to try to measure NDMA production 9 from these exogenous substances, right? 10 A. . 02:58 PM 11 Q. And would you agree that the level 12 of NDMA in a human's gastric system, in part, 13 depends on their diet? 14 A. Yes, diet could affect the NDMA 15 level. 02:58 PM 16 Q. And different people will consume 17 different levels of NDMA and thus have 18 different levels of NDMA in their system, 19 correct? 20 A. Correct. 02:58 PM 21 Q. And the bodies DNA repair 22 mechanism is -- has the capacity to repair 23 that range of exposure from these very diets 24 in humans, you would agree with that? 25 MR. NIGH: Form objection. 02:58 PM</p>
<p style="text-align: right;">Page 231</p> <p>1 identification.) 2 BY MR. FOWLER: 3 Q. Doctor, before you is an article 4 by -- first author is Krul, it's a 2004 5 article that you cite as Footnote 283 in your 02:56 PM 6 report. And I ask you, do you recognize this 7 article? You've reviewed it, sir? 8 A. Yes. 9 Q. And in some -- this article 10 constructed a model for -- to simulate the 02:57 PM 11 gastrointestinal process for humans, correct? 12 A. Correct. 13 Q. And then it introduced some 14 exogenous sources to attempt to measure the 15 amount of NDMA produced from the nitrate, the 02:57 PM 16 dimethylamine or the cod fish, which were 17 simultaneously introduced, correct? 18 A. Yes. 19 Q. And under these conditions, the 20 cumulative amounts of NDMA formed were -- 02:57 PM 21 ranged from 2.3 to 422 milligrams of NDMA, 22 correct? 23 A. I think microgram. 24 Q. Was it microgram or milligram? 25 A. It says microgram. 02:57 PM</p>	<p style="text-align: right;">Page 233</p> <p>1 A. Well, yeah, it depends -- so 2 that's when a body has enzymes to repair the 3 DNA. But whether it can do it in a specific 4 case, it would depend on that specific case. 5 BY MR. FOWLER: 02:59 PM 6 Q. Fair enough. And you would agree 7 that the human -- let me start that again. 8 Is it within your specialty to 9 understand the development of the human 10 antitoxicity system that the liver and the 02:59 PM 11 enzymes have evolved to? Is that within your 12 area? 13 A. Yeah, but it depends which way 14 you're going, yeah. 15 Q. And you would agree that the liver 02:59 PM 16 has evolved over time to be able to keep 17 bodies alive for longer based upon the 18 different toxicities that have been 19 introduced to humans since cavemen invited 20 fire? 02:59 PM 21 A. Right. The cytochrome P450 22 enzymes which generate these metabolites from 23 NDMA and NDEA are highly expressed in the 24 liver, and that's one of their normal 25 functions is to detoxify carcinogens and even 03:00 PM</p>

<p style="text-align: right;">Page 234</p> <p>1 alcohol and other substances we take in the 2 body. 3 Q. Okay. Let me have this one, 4 please. 5 And, Doctor, do you know whether 03:00 PM 6 N-nitrosamines are produced from amino acids? 7 A. So the nitrosamines are -- it 8 depends on the context, they can be. 9 Q. Okay. Thank you. 10 And it works by nitrosation of 03:00 PM 11 amino acids by nitrosating agents like a 12 nitrite, correct? 13 A. Correct. 14 Q. And that is something that humans 15 can be exposed to from various things in 03:00 PM 16 their diet, vegetables, fruits even have 17 nitrites, right? 18 A. Correct. 19 Q. And the level of nitrites 20 introduced can affect the level of NDMA in 03:00 PM 21 anybody's body that consumes those, right? 22 A. Yes. 23 Q. Okay. And would you agree that 24 ingested nitrites can be converted -- I'm 25 sorry. Do you agree that ingested nitrates 03:01 PM</p>	<p style="text-align: right;">Page 236</p> <p>1 to show, is there endogenous NDMA formation 2 and it gets back to that -- there's no 3 reliable or -- reliable way to measure it. 4 And in this case, like I said before, the 5 biologically relevant question is does 03:02 PM 6 exogenous NDMA cause the cancer. 7 Q. Why is that the biologically 8 relevant question, if everyone -- if it's not 9 disputed that some level of endogenous NDMA 10 is formed, why doesn't the biological 03:02 PM 11 question include that? 12 A. Because I was asked -- I wasn't 13 asked in the general population of all of us 14 wondering around with our endogenous levels 15 or whatever mediator, does everybody get 03:02 PM 16 cancer. And we know and actually depending 17 on the cancer type, the rates, one out of 18 eight in prostate cancer. 19 I was asked does exogenous NDMA 20 and NDEA in a valsartan pill, that you take 03:02 PM 21 orally, so by exogenous methods, does that 22 cause human cancer. 23 So -- and also, there's no -- like 24 I keep saying, there's no biological reliable 25 way to quantify the NDMA endogenously in the 03:03 PM</p>
<p style="text-align: right;">Page 235</p> <p>1 can be converted to nitrites in the mouth? 2 A. In the -- 3 Q. In your salivary system. 4 Am I within your specialty still 5 here? 03:01 PM 6 MR. NIGH: Form objection. 7 A. Yes, it should be able to be 8 converted, but I -- 9 BY MR. FOWLER: 10 Q. So would you agree, Doctor, that 03:01 PM 11 N-nitrosamines can be formed inside the body 12 after ingesting amino acids in proteins and 13 nitrates in fruits and vegetables? 14 A. So this is where -- a key 15 difference here. This isn't an in-vitro 03:01 PM 16 model. So one of the things in science we do 17 is we study in vitro and in vivo. 18 Q. I'm sorry. I'm past that exhibit. 19 A. Oh, okay. 20 Q. Yeah, you can set that aside. 03:01 PM 21 A. I thought you were referring to 22 this. 23 Q. No, sir. 24 A. Oh, so what I was trying to say is 25 that it comes back to -- what's important is 03:01 PM</p>	<p style="text-align: right;">Page 237</p> <p>1 body. Now, people study it. Like you showed 2 the Krul paper in an in vitro system but that 3 doesn't mimic -- in the end of the day 4 in vivo is what people want to see. 5 Q. Doctor, here's my -- sorry. 03:03 PM 6 Doctor, you would -- do you agree that 7 N-nitrosamines can be formed inside the body 8 after ingesting amino acids in proteins and 9 nitrates in fruit? 10 A. I would say it can be formed, but 03:03 PM 11 I don't see how it's relevant to the case 12 here. 13 Q. Okay. Well, that's all right. 14 And you would agree that that 15 occurs independently of eating processed 03:03 PM 16 meats, grilled barbecue, or any of those 17 NDMA-containing dietary items that you've 18 seen in your studies, you would agree? 19 A. I missed -- independently? 20 Q. Yes, sir. 03:04 PM 21 A. So usually there's certain foods 22 that are higher in -- 23 Q. I'll ask -- I'm sorry. Let me ask 24 the question again. I may not -- let me just 25 ask it again. 03:04 PM</p>

<p style="text-align: right;">Page 238</p> <p>1 Do you agree that this production 2 of N-nitrosamines occurs independently of 3 eating processed meats? 4 A. I would have to see a publication. 5 What I've seen is you give some type of meat 03:04 PM 6 or -- and then you look at the levels. 7 Q. Okay. Well, we agreed -- or you 8 agreed that N-nitrosamines can be formed 9 after ingesting amino acids from proteins and 10 nitrates from fruit, right? 03:04 PM 11 A. Correct. 12 Q. And that process occurs 13 independent of whether or not somebody has 14 eaten processed meats? 15 A. Yes. 03:05 PM 16 Q. Okay. And do you agree, then, 17 that those -- that N-nitrosamines from amino 18 acids commonly occur in the human body? 19 A. Like I said, it could occur in the 20 body, but I don't see how that is relevant. 03:05 PM 21 MR. NIGH: How much longer do you 22 want to go till a break? 23 MR. FOWLER: It's up to you, 24 Counsel. 25 Actually, it's up to you, 03:05 PM</p>	<p style="text-align: right;">Page 240</p> <p>1 email says a correction has been 2 uploaded to the Dropbox but it wasn't 3 isolated and it was sent at 4:57 4 yesterday. 5 So to the extent this needs to be 03:35 PM 6 revisited, I'm going to reserve on this, 7 because I don't have time to process 8 this today. But I want to point out 9 clarification of what was explained 10 earlier, that it was 4:57 yesterday. 03:36 PM 11 MR. NIGH: Yeah, I'll just point 12 out that it clearly states at the bottom 13 that it's corrections and it's uploaded 14 so -- to the Dropbox. 15 MR. FOWLER: Amongst all the 03:36 PM 16 other, yes, sir. 17 MR. NIGH: Sure. 18 MR. FOWLER: This is an original 19 sticker. I don't like keeping those. 20 Let's put that back, Doctor. 03:36 PM 21 THE WITNESS: Thank you. 22 MR. FOWLER: This is mine. 23 Let's mark Number 11. 24 / 25 / 03:36 PM</p>
<p style="text-align: right;">Page 239</p> <p>1 Dr. Panigrahy. 2 THE WITNESS: We're together. You 3 decide. 4 MR. FOWLER: How long have we been 5 going, like an hour and a half? Let's 03:05 PM 6 take a break then, that's fine, for 7 madam court reporter, please. 8 THE VIDEOGRAPHER: The time is 9 3:04. We're off the record. 10 (Recess taken at 3:04 p.m. to 3:34 p.m.) 03:05 PM 11 THE VIDEOGRAPHER: The time is 12 3:34. We're back on the record. 13 MR. FOWLER: Before we return to 14 the questioning, I want to circle back 15 on Exhibit 8, which was Dr. Panigrahy's 03:35 PM 16 correction list, and I want to note that 17 this was sent in an email at 4:57 18 yesterday. It was sent with the subject 19 "Studies per your request," from Dolores 20 DeSalvo, who I don't know. It doesn't 03:35 PM 21 reference valsartan, it doesn't 22 reference Dr. Panigrahy, and worse, it 23 adds this document to the other 500 that 24 were in the drop on Tuesday, without any 25 reference that there's something -- the 03:35 PM</p>	<p style="text-align: right;">Page 241</p> <p>1 (Exhibit 11, Endogenous versus exogenous 2 exposure to N-nitroso compounds and gastric 3 cancer risk in the European Prospective 4 Investigation into Cancer and Nutrition 5 (EPIC-EURGAST) study, marked for 03:36 PM 6 identification.) 7 MR. NIGH: Yeah, we were also 8 going to note, that the company 9 documents were uploaded to the Dropbox 10 as the full production on September 7th. 03:37 PM 11 So that information is already in 12 there. 13 MR. FOWLER: Thank you. We were 14 looking for clarification on that. I 15 think I said I didn't recall if they 03:37 PM 16 were there, and I asked him if they 17 were, but thank you for that. I 18 appreciate it. 19 MR. NIGH: You're welcome. 20 MR. FOWLER: Here's two copies of 03:37 PM 21 Exhibit 11. 22 BY MR. FOWLER: 23 Q. Before you, Dr. Panigrahy, is 24 Exhibit 11, and let me ask you first, are you 25 familiar with the journal "Carcinogenesis"? 03:37 PM</p>

<p style="text-align: right;">Page 242</p> <p>1 A. Yes.</p> <p>2 Q. Is that a reputable journal?</p> <p>3 A. Yes.</p> <p>4 Q. Have you published in that?</p> <p>5 A. I personally haven't, but I've 03:37 PM</p> <p>6 read papers in there.</p> <p>7 Q. Yes, sir. And this article is</p> <p>8 entitled "Endogenous Versus Exogenous</p> <p>9 Exposure to N-Nitroso Compounds and Gastric</p> <p>10 Cancer Risk in the European Prospective 03:38 PM</p> <p>11 Investigation into Cancer and Nutrition, the</p> <p>12 EPIC-EURGAST study." And this is from March</p> <p>13 of 200-6. The lead author is Paula Jakszyn,</p> <p>14 J-a-k-s-z-y-n.</p> <p>15 Have you seen this document 03:38 PM</p> <p>16 before, Doctor, this article?</p> <p>17 A. Yes.</p> <p>18 Q. And I note that you did not</p> <p>19 include it in the 583 references in your</p> <p>20 report, did you? 03:38 PM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A. Let me just check. So when I did</p> <p>23 epi studies with gastric cancer, I relied on</p> <p>24 several studies, one was Song, which was a</p> <p>25 meta-analysis of 11 different epi studies and 03:38 PM</p>	<p style="text-align: right;">Page 244</p> <p>1 And then I also mentioned Palli, Loh,</p> <p>2 Knekt, Keszei, and I actually did say</p> <p>3 Jakszyn studies. But as far as</p> <p>4 citations with all the references, it</p> <p>5 looks like I cited Song, De Stefani, 03:43 PM</p> <p>6 Pobel, La Vecchia, and Keszei I did</p> <p>7 cite.</p> <p>8 BY MR. FOWLER:</p> <p>9 Q. Thank you for confirming that.</p> <p>10 And you said you -- did you say 03:43 PM</p> <p>11 that Knekt -- the K-n-e-k-t study was one of</p> <p>12 them?</p> <p>13 A. I did mention Knekt in the gastric</p> <p>14 section.</p> <p>15 Q. Okay. Thank you. 03:43 PM</p> <p>16 So, Doctor, directing your</p> <p>17 attention to page 1499 of this study, under</p> <p>18 the discussion section. Are you with me,</p> <p>19 sir?</p> <p>20 A. Yes. 03:43 PM</p> <p>21 Q. If you look at the -- the last</p> <p>22 sentence of the paragraph on the first column</p> <p>23 leading over to the second column, it says</p> <p>24 "There is only one other cohort study that</p> <p>25 has investigated the association between NDMA 03:43 PM</p>
<p style="text-align: right;">Page 243</p> <p>1 then I cited several other studies.</p> <p>2 BY MR. FOWLER:</p> <p>3 Q. Okay. I'm only going to talk</p> <p>4 about this study for the next few minutes,</p> <p>5 sir. So we can agree, and it sounds like you 03:39 PM</p> <p>6 would agree that it's not one of the</p> <p>7 references in your report, correct, sir?</p> <p>8 MR. NIGH: Form objection.</p> <p>9 BY MR. FOWLER:</p> <p>10 Q. Your report speaks for itself. 03:39 PM</p> <p>11 A. Let me just -- actually, let me</p> <p>12 check. I thought I had cited gastric cancer.</p> <p>13 MR. FOWLER: Let's go off the</p> <p>14 record. The doctor -- while you look</p> <p>15 through your report -- 03:40 PM</p> <p>16 THE VIDEOGRAPHER: The time is</p> <p>17 3:39. We're off the record.</p> <p>18 (Recess taken at 3:39 p.m. to 3:41 p.m.)</p> <p>19 THE VIDEOGRAPHER: The time is</p> <p>20 3:41, we're back on the record. 03:42 PM</p> <p>21 THE WITNESS: Correct, it looks</p> <p>22 like I didn't cite the Jakszyn 200-6. I</p> <p>23 mentioned in the gastric section of my</p> <p>24 report the Song meta-analysis and then</p> <p>25 De Stefani, Pobel, La Vecchia, Larson. 03:42 PM</p>	<p style="text-align: right;">Page 245</p> <p>1 and GC, gastric cancer, and no association</p> <p>2 was found."</p> <p>3 Do you see where I read that,</p> <p>4 sir?</p> <p>5 A. Yes. 03:44 PM</p> <p>6 MR. NIGH: Form objection.</p> <p>7 BY MR. FOWLER:</p> <p>8 Q. And that refers to the study that</p> <p>9 you were referencing, doesn't it, sir? 16,</p> <p>10 if you look -- 03:44 PM</p> <p>11 A. Yes. Yes.</p> <p>12 Q. And could this be the reason why</p> <p>13 you didn't include Jakszyn in your</p> <p>14 references?</p> <p>15 MR. NIGH: Form objection. 03:44 PM</p> <p>16 A. So I did include Jakszyn -- so</p> <p>17 when I went through the epi studies for the</p> <p>18 diet, first I started with Song, the</p> <p>19 meta-analysis, and then I included the</p> <p>20 De Stefani, Pobel, La Vecchia, Larson, Palli, 03:44 PM</p> <p>21 Loh, Knekt, Keszei, and Jakszyn. However,</p> <p>22 I -- with 583 citations, I cited about three</p> <p>23 or four from this one section.</p> <p>24 BY MR. FOWLER:</p> <p>25 Q. Right. And, you know, amongst the 03:44 PM</p>

<p style="text-align: right;">Page 246</p> <p>1 citations that you cited, you included one on</p> <p>2 the inflammatory properties of polygranate</p> <p>3 fruit, right, that was one of the ones did</p> <p>4 include?</p> <p>5 MR. NIGH: Form objection. 03:45 PM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. Do you recall that, Doctor, on</p> <p>8 inflammation, you reference is it pomegranate</p> <p>9 or polygranate? Pomegranate, I haven't tried</p> <p>10 it myself. 03:45 PM</p> <p>11 A. Which reference?</p> <p>12 Q. You reference a pomegranate study</p> <p>13 about inflammation, but you don't reference</p> <p>14 this study on N-nitroso compounds and gastric</p> <p>15 cancer risk; is that correct? 03:45 PM</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A. So I cited to De Stefani, Pobel,</p> <p>18 La Vecchia, and Larson that had statistical</p> <p>19 significant findings, I cited. And then I</p> <p>20 did cite Song, the meta-analysis, and then -- 03:45 PM</p> <p>21 I'm sorry, the pomegranate?</p> <p>22 BY MR. FOWLER:</p> <p>23 Q. I'm sorry. Let me withdraw that.</p> <p>24 But, Doctor, the Keszei study, do</p> <p>25 you cite it in your report for the 03:46 PM</p>	<p style="text-align: right;">Page 248</p> <p>1 say that in your report when you refer to</p> <p>2 that study?</p> <p>3 MR. NIGH: Form objection. It's</p> <p>4 on page --</p> <p>5 A. Well, I say nonsignificant 03:47 PM</p> <p>6 increase for Palli, for Loh, nonsignificant</p> <p>7 increase. Jakszyn studies did not. So</p> <p>8 what's important is that this is in the</p> <p>9 context of with Hidajat, which was the</p> <p>10 paragraph before, and then I mentioned 03:47 PM</p> <p>11 De Stefani, Pobel, La Vecchia and Larson.</p> <p>12 BY MR. FOWLER:</p> <p>13 Q. Okay. Thank you. Now let's</p> <p>14 return to this article, please, this Jakszyn</p> <p>15 200-6, same page where the discussion is, 03:47 PM</p> <p>16 sir.</p> <p>17 The first sentence, "This is the</p> <p>18 first study," -- and here we are at 200-6.</p> <p>19 "This is the first study reporting</p> <p>20 relationships between both endogenous and 03:47 PM</p> <p>21 exogenous exposure to NOC's."</p> <p>22 Can we agree those are nitroso</p> <p>23 compounds?</p> <p>24 A. Yes.</p> <p>25 Q. And it says, the next sentence, 03:48 PM</p>
<p style="text-align: right;">Page 247</p> <p>1 proposition that it did find an association</p> <p>2 of gastric cancer and NDMA?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. So the Keszei had an increase in</p> <p>5 men. I wanted to include -- in my analysis, 03:46 PM</p> <p>6 I didn't want to cherry-pick. I wanted to</p> <p>7 include all the studies. So -- and that's</p> <p>8 what I did here in this statement where it</p> <p>9 says "in the Song meta-analysis I included</p> <p>10 the De Stefani, Pobel, La Vecchia, Larson, 03:46 PM</p> <p>11 Palli, Loh, Knekt, Keszei, Jakszyn. So with</p> <p>12 having almost 600 references, it was -- it</p> <p>13 was -- you know, the Song -- the</p> <p>14 meta-analysis of 11 studies covered many of</p> <p>15 these studies. 03:46 PM</p> <p>16 BY MR. FOWLER:</p> <p>17 Q. Yes, sir. With so many</p> <p>18 references, it's kind of hard to -- as we saw</p> <p>19 from Exhibit 8, it's hard for that many</p> <p>20 references without some mistakes, correct? 03:47 PM</p> <p>21 A. Correct.</p> <p>22 Q. And am I correct that you don't</p> <p>23 say in your report that the Keszei study that</p> <p>24 investigated the association between NDMA and</p> <p>25 gastric cancer found no association; do you 03:47 PM</p>	<p style="text-align: right;">Page 249</p> <p>1 "The exposure of NDMA from food was less than</p> <p>2 1 microgram a day, whereas that from</p> <p>3 endogenous nitrosos was 93 micrograms a day."</p> <p>4 Did I read that correctly, sir?</p> <p>5 A. Correct. 03:48 PM</p> <p>6 Q. And if you look down in Table 1,</p> <p>7 we see that -- do you see the ENOC line at</p> <p>8 93.05?</p> <p>9 A. Right.</p> <p>10 Q. That's referring to micrograms, 03:48 PM</p> <p>11 yes?</p> <p>12 A. Yes.</p> <p>13 Q. And if we were to translate that</p> <p>14 to nanograms, that would be 93,000 nanograms</p> <p>15 of nitroso compounds endogenously produced, 03:48 PM</p> <p>16 according to this study, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And amongst those N-nitroso</p> <p>19 compounds, you would agree that NDMA would be</p> <p>20 included in that, correct? 03:48 PM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A. What's -- yes, NDMA is one of the</p> <p>23 members of the family. However, what's</p> <p>24 important in these studies is we -- the</p> <p>25 studies that quantify the amount of NDMA was 03:49 PM</p>

<p style="text-align: right;">Page 250</p> <p>1 the important part.</p> <p>2 And also I'll add, that we don't</p> <p>3 use one study as a conclusion. We use a</p> <p>4 series of studies. So the fact that Song</p> <p>5 meta-analysis was significant and the fact 03:49 PM</p> <p>6 that De Stefani, Pobel, La Vecchia and Larson</p> <p>7 all had statistical increases, those are four</p> <p>8 separate epi studies, and that's with diet,</p> <p>9 and that in conjunction with Hidajat, which</p> <p>10 had significant -- significance of 03:49 PM</p> <p>11 association between inhalation and mortality.</p> <p>12 BY MR. FOWLER:</p> <p>13 Q. Yes, sir, respectfully, there</p> <p>14 wasn't -- I didn't have a question pending.</p> <p>15 A. Okay. 03:50 PM</p> <p>16 Q. Now, let me direct your attention</p> <p>17 to what will be marked as Exhibit 12.</p> <p>18 (Exhibit 12, DNA adducts in humans after</p> <p>19 exposure to methylating agents, marked for</p> <p>20 identification.) 03:50 PM</p> <p>21 BY MR. FOWLER:</p> <p>22 Q. Now, Dr. Panigrahy, do you agree</p> <p>23 that the -- let me start that again.</p> <p>24 Do you agree that a marker of the</p> <p>25 presence of NDMA is the DNA adduct, the 03:50 PM</p>	<p style="text-align: right;">Page 252</p> <p>1 induce cell death. And that's how cell</p> <p>2 death -- and it can be from DNA.</p> <p>3 We've actually looked for</p> <p>4 circulating tumor cells from the DNA in the</p> <p>5 blood. Because one of the -- when we 03:52 PM</p> <p>6 translate a cancer drug from the lab to the</p> <p>7 clinic, one of the important things we look</p> <p>8 for is biomarkers when a cancer patient gets</p> <p>9 a drug, how do you know your drug is working.</p> <p>10 So what we model, and we work very closely 03:52 PM</p> <p>11 with the oncologists, is what are these</p> <p>12 systemic markers, whether they're in the</p> <p>13 blood or in the tissue, and ideally in the</p> <p>14 blood, and what's a marker of the drug</p> <p>15 efficacy. 03:53 PM</p> <p>16 Q. Right. Doctor, apoptotic cell</p> <p>17 death --</p> <p>18 THE REPORTER: A what?</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. Apoptotic, A-p-o-p-t-o-t-i-c, I 03:53 PM</p> <p>21 think, that is not the same as looking at DNA</p> <p>22 strands and DNA breakage, is it, sir?</p> <p>23 MR. NIGH: Form objection.</p> <p>24 A. DNA strands can generate --</p> <p>25 / 03:53 PM</p>
<p style="text-align: right;">Page 251</p> <p>1 0-6-methylguanine adduct is a marker of NDMA</p> <p>2 metabolism?</p> <p>3 A. Yes.</p> <p>4 Q. And scientists don't dispute that,</p> <p>5 correct? 03:51 PM</p> <p>6 A. Correct.</p> <p>7 Q. It's a unique adduct that can be</p> <p>8 identified and quantified by scientists,</p> <p>9 correct?</p> <p>10 A. It's not specific to NDMA 03:51 PM</p> <p>11 metabolism, in the context of giving NDMA,</p> <p>12 it's a marker. However, you can see these</p> <p>13 adducts in other situations.</p> <p>14 Q. Yes, sir.</p> <p>15 And, Doctor, in your work, in your 03:51 PM</p> <p>16 professional work outside of this litigation,</p> <p>17 do you look at DNA in your laboratory?</p> <p>18 A. Yes. One of our discovery was</p> <p>19 that DNA cell death can be a marker of tumor</p> <p>20 growth. And we actually showed in several 03:52 PM</p> <p>21 publications that that cell death from DNA,</p> <p>22 which can be necrotic cell death or apoptotic</p> <p>23 cell death can actually stimulate tumor</p> <p>24 growth, which is a little paradoxical,</p> <p>25 because cancer therapy, that's the goal to 03:52 PM</p>	<p style="text-align: right;">Page 253</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. Correct.</p> <p>3 A. -- them. Cell damage that can</p> <p>4 lead to apoptotic cell death.</p> <p>5 Q. Yes, sir. 03:53 PM</p> <p>6 A. So there's a lot of interplay</p> <p>7 between DNA damage, oxidative stress,</p> <p>8 inflammation, and apoptotic cell death.</p> <p>9 They're very interlinked.</p> <p>10 Q. I understand. But what your lab 03:53 PM</p> <p>11 looks at is the artifacts, if you will, the</p> <p>12 byproduct of cell death, whether it's</p> <p>13 apoptotic, whether it's debris from necrosis,</p> <p>14 but you don't actually look at DNA breaks in</p> <p>15 your lab or mistranscriptions, do you? 03:53 PM</p> <p>16 A. Correct. Now that's a</p> <p>17 different -- so like --</p> <p>18 Q. Yes.</p> <p>19 A. -- those assays we don't do.</p> <p>20 Q. And to be clear, you don't do the 03:54 PM</p> <p>21 assays that would recognize a CG/AT</p> <p>22 mistranscription? You don't actually see</p> <p>23 those in your lab, right?</p> <p>24 A. Correct.</p> <p>25 Q. And you don't actually evaluate 03:54 PM</p>

<p style="text-align: right;">Page 254</p> <p>1 DNA repair in your lab, do you?</p> <p>2 A. We -- correct. But like I said,</p> <p>3 it's a little -- all these processes mix</p> <p>4 together and they all play together. So</p> <p>5 we'll look at the endpoint of DNA damage and 03:54 PM</p> <p>6 we'll look at that by PCR, by protein.</p> <p>7 Q. Sure. But when you look at the</p> <p>8 end product of a cell death, you don't know</p> <p>9 what exactly happened to the DNA or even if</p> <p>10 the DNA was the cause of the apoptosis, 03:54 PM</p> <p>11 correct?</p> <p>12 A. Well, we do carefully planned</p> <p>13 experiments where we will induce the cell</p> <p>14 death in certain cells and -- yeah.</p> <p>15 Q. Okay. So let's get back to the 03:55 PM</p> <p>16 this article by Dr. Kyrtopoulos, "DNA Adducts</p> <p>17 in Humans After Exposure to Methylating</p> <p>18 Agents."</p> <p>19 We agree that NDMA and -- let me start</p> <p>20 that again. 03:55 PM</p> <p>21 We agree NDMA is a methylating agent,</p> <p>22 correct?</p> <p>23 A. Yes.</p> <p>24 Q. That's where the M comes from?</p> <p>25 A. Yes. 03:55 PM</p>	<p style="text-align: right;">Page 256</p> <p>1 of the abstract, it states that "the high</p> <p>2 incidence of methylated DNA adducts, even in</p> <p>3 humans thought not to have suffered extensive</p> <p>4 exposure to environmental methylating agents</p> <p>5 implies that chemicals of endogenous origin, 03:57 PM</p> <p>6 probably N-nitroso compounds such as the</p> <p>7 strongly carcinogenic NDMA, may be primarily</p> <p>8 responsible for their formation and raises</p> <p>9 questions of carcinogenic risks associated</p> <p>10 with such exposure." 03:57 PM</p> <p>11 Do you agree with that, Doctor?</p> <p>12 A. Yes.</p> <p>13 Q. And I think, correct me if I'm</p> <p>14 wrong, I think we are in agreement that these</p> <p>15 adducts are what you refer to as biomarkers 03:57 PM</p> <p>16 for NDMA -- for an NDMA-metabolized mutation,</p> <p>17 right?</p> <p>18 A. Right, they're not just</p> <p>19 biomarkers. They can initiate the cancer.</p> <p>20 So they have a very important process in 03:57 PM</p> <p>21 the -- how NDMA can cause cancer.</p> <p>22 Q. Yes, sir, and we will probably</p> <p>23 talk about that. But for right now I'm just</p> <p>24 trying to get us on the same page. That the</p> <p>25 adducts that are observed are a marker for a 03:58 PM</p>
<p style="text-align: right;">Page 255</p> <p>1 Q. And the EA an alkylating agent,</p> <p>2 right?</p> <p>3 A. Right.</p> <p>4 Q. And --</p> <p>5 A. Actually, that's where the ethyl 03:55 PM</p> <p>6 comes up. They're both alkylating, but ethyl</p> <p>7 is NDEA, methyl is NDMA.</p> <p>8 Q. I almost sounded like I knew what</p> <p>9 I was saying until you corrected me. Thank</p> <p>10 you, Doctor. 03:55 PM</p> <p>11 Okay. So that's the title of the</p> <p>12 article. Let's look at the abstract, sir,</p> <p>13 and directing your attention to the last</p> <p>14 sentence. "Based on the dosimetry of adduct</p> <p>15 accumulation in rats chronically exposed to 03:56 PM</p> <p>16 very low doses of NDMA, it is suggested that</p> <p>17 the exposure needed to account for the levels</p> <p>18 of adducts found in human DNA may be of the</p> <p>19 order of hundreds of micrograms NDMA or</p> <p>20 equivalent per day. A level of exposure 03:56 PM</p> <p>21 which may well represent a significant</p> <p>22 carcinogenic hazard for man."</p> <p>23 Do you see that?</p> <p>24 A. Yeah.</p> <p>25 Q. And when we look at the beginning 03:56 PM</p>	<p style="text-align: right;">Page 257</p> <p>1 level of -- for the level of NDMA, according</p> <p>2 to this article, correct?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. Correct.</p> <p>5 BY MR. FOWLER: 03:58 PM</p> <p>6 Q. And this is an article that you</p> <p>7 cite and rely upon in your report?</p> <p>8 A. Correct. But I'll say one of the</p> <p>9 things we put in a context is that when we</p> <p>10 talk about adducts, you have to talk about in 03:58 PM</p> <p>11 the context of an experiment, whether it's</p> <p>12 in vivo giving a carcinogen to cause a tumor.</p> <p>13 You have to relate it to the tumor or you</p> <p>14 relate it to a certain activity. Just the</p> <p>15 presence of an adduct, it's important to put 03:58 PM</p> <p>16 a metabolite in the context of the</p> <p>17 experiment.</p> <p>18 Q. Doctor, scientists agree that the</p> <p>19 presence of the O-6 mg, can I call it that?</p> <p>20 A. Yeah. 03:58 PM</p> <p>21 Q. The O-6 mg is a marker of NDMA's</p> <p>22 presence in the cell, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And if you look at the second page</p> <p>25 of this article, sir, it's 136 at the top of 03:59 PM</p>

<p style="text-align: right;">Page 258</p> <p>1 the first column -- actually, start it on the 2 first page, bottom of the thing -- bottom of 3 the column, it says "Additional human 4 exposure to NDMA is derived from endogenous 5 formation in the stomach and/or other body 03:59 PM 6 compartments. Accurate direct estimation of 7 endogenous exposure to NDMA is not possible, 8 but based on indirect evidence it's been 9 suggested that this mode of exposure may 10 greatly exceed that arising from exogenous 03:59 PM 11 sources." 12 Did I read that correctly? 13 A. Yes. 14 Q. And do you agree with that, sir? 15 A. No. 03:59 PM 16 Q. So you cited this article for some 17 other purpose? 18 A. So when you cite an article, you 19 don't -- that doesn't necessarily mean you 20 agree with every sentence in this article. 03:59 PM 21 So I would agree that accurate 22 direct estimation of endogenous NDMA is not 23 possible; that's what we know. But I would 24 have to see evidence that this mode of 25 exposure, since it's biologically pretty 04:00 PM</p>	<p style="text-align: right;">Page 260</p> <p>1 for identification.) 2 THE WITNESS: Can I add something 3 else? 4 MR. FOWLER: I haven't asked a 5 question, sir. 04:02 PM 6 THE WITNESS: Okay. 7 BY MR. FOWLER: 8 Q. Before you, sir, is Exhibit 13, 9 which I will submit is FDA's published 10 summary from the Nitrosamines as Impurities - 04:02 PM 11 Health Risk Assessment Mitigation public 12 workshop, held March 29, 30, 2021. 13 First of all, did you attend or 14 watch that workshop, sir? 15 A. No, I did not. 04:02 PM 16 Q. Have you seen this document 17 before? 18 A. I don't think so, no. 19 Q. Okay. You just testified that 20 the -- as I've said before, what's relevant 04:02 PM 21 here, does exogenous NDMA in the valsartan 22 tablet cause human cancer. The question 23 wasn't does endogenous NDMA cause cancer; 24 that's what you testified to. And now let me 25 direct to you page 4 of the summary, please. 04:03 PM</p>
<p style="text-align: right;">Page 259</p> <p>1 impossible to measure the endogenous NDMA's. 2 It's technically not possible to make the 3 conclusion that it may greatly exceed that 4 from exogenous sources, which, in a 5 scientific publication, you can say may and 04:00 PM 6 they cite reference 7, a model for estimation 7 of human exposure to endogenous, 1980, that's 8 a model. So many people have tried to model 9 endogenous formation, either in vivo or -- 10 yeah, in the body, but we have to be careful 04:00 PM 11 with modeling. 12 In the end, it's very important, 13 in vivo is to have an accurate estimation -- 14 measure of the amount of endogenous NDEA, and 15 that's not possible here. 04:01 PM 16 And also, I would just add, and 17 I've said this before, what's relevant here 18 is those exogenous NDMA in the valsartan 19 tablet caused human cancer. The question 20 wasn't does endogenous NDMA cause cancer. 04:01 PM 21 MR. FOWLER: Exhibit 12. 22 THE REPORTER: No, 13. 23 (Exhibit 13, Nitrosamines as Impurities in 24 Drugs - Health Risk Assessment and Mitigation 25 Public Workshop, March 29-30, 2021, marked 04:02 PM</p>	<p style="text-align: right;">Page 261</p> <p>1 Are you there? 2 A. Yes. 3 Q. Thank you. At the bottom of the 4 page, that last paragraph, it says "In 5 addition to their abundance in the 04:03 PM 6 environment, nitrosamines are formed 7 endogenously. To calculate risk, it is 8 imperative to determine endogenous formation 9 and understand the pharmacokinetics of 10 nitrosamines formation and distribution." 04:03 PM 11 Do you see that, sir? 12 A. Yes. 13 Q. So do you disagree with the FDA? 14 A. So I agree that in 2021 this is a 15 very important question to determine 04:03 PM 16 endogenous formation, and I agree with this 17 panel. 18 Currently, we don't have an 19 accurate way to measure endogenous NDMA. And 20 actually in the diets -- in some of the 04:04 PM 21 studies like Hidajat, the NDMA not only can 22 come from inhalation, but it can come from 23 somebody eating NDMA in the diet. 24 So what I'm saying is, in science 25 you meet, in 2021, and this is a very 04:04 PM</p>

<p style="text-align: right;">Page 262</p> <p>1 important question, but currently the 2 regulatory agencies, such as the FDA, the EMA 3 and the DMA in their 2020 report wrote, "It 4 is important to know the endogenous levels of 5 NDMA, but there's no assay to detect it." 04:04 PM 6 So there's no reliable way to know 7 it. And this is where a group of talented 8 scientists are meeting to answer a question, 9 what is the endogenous level of NDMA, but we 10 don't have an accurate method to quantify 04:05 PM 11 that. 12 MR. NIGH: And I just wanted to 13 object to the form of that question. 14 Go ahead. 15 BY MR. FOWLER: 04:05 PM 16 Q. Directing your attention to page 17 27, sir, third paragraph. "DNA adducts were 18 indicated by the expert panelists as the best 19 biomarkers of exposure for nitrosamines 20 because they can be reliably quantified using 04:05 PM 21 highly sensitive analytic methods." 22 Do you see that, sir? 23 A. Yes. 24 Q. And do you agree with that? 25 A. Yes. So we can quantify NDMA 04:05 PM</p>	<p style="text-align: right;">Page 264</p> <p>1 measured by virtue of the adduct which can be 2 quantified? 3 MR. NIGH: Form objection. 4 A. So it's different to measure the 5 adduct as a biomarker versus endogenous NDMA. 04:06 PM 6 So that's a different question. Here, 7 they're trying to use it as a biomarker of 8 exposure for nitrosamines. 9 So the question that you asked 10 before is endogenous NDMA, that's an entirely 04:07 PM 11 different question. It is possible to 12 measure DNA adducts in tissues and blood and 13 use that as a biomarker. So that's what we 14 try to do all the time in science is -- 15 that's what I was mentioning in the lab and 04:07 PM 16 when we translate in patients. We try to 17 find biomarkers that reflect the activity of 18 a certain drug, but that's not the level of 19 the endogenous NDMA that's in the body. 20 BY MR. FOWLER: 04:07 PM 21 Q. Can we agree, Doctor, that the mg 22 O-6 is the mutation that is -- that NDMA 23 forms on the -- on DNA, correct? 24 A. So, actually, 65 percent of the 25 adducts that are formed are N7-methylguanine. 04:07 PM</p>
<p style="text-align: right;">Page 263</p> <p>1 adducts. I cited in my report many papers 2 that give NDMA, for example, in the monkey 3 and four hours later you can detect -- in 32 4 different tissues DNA adducts. 5 Q. Yes, sir. This is saying -- and 04:05 PM 6 you agree that you can detect the mg O-6 7 adduct in humans and that can be quantifiably 8 measured, yes? 9 A. Yes. I cited, right. 10 Q. You agree? 04:06 PM 11 A. I cited even the 1970 papers that 12 I mentioned, they measured the adducts. 13 Q. And in 2021, the expert panelists, 14 which included one of Plaintiffs' experts 15 Dr. Hecht, agreed that the mg O-6 adduct is 04:06 PM 16 the best way to quantify the endogenous 17 production of NDMA, correct? 18 MR. NIGH: Form objection. 19 BY MR. FOWLER: 20 Q. Were you aware of that, sir? 04:06 PM 21 A. I'm not sure where you're reading. 22 Q. It's the same place. I just want 23 to confirm that you were aware that the FDA 24 panel, including Plaintiffs' expert 25 Dr. Hecht, agreed that endogenous NDMA can be 04:06 PM</p>	<p style="text-align: right;">Page 265</p> <p>1 Q. Right. 2 A. And 7 percent is 3 O-6-methylguanine, and there's about three or 4 four other methylguanines. There's three or 5 four other types that make up the hundred 04:08 PM 6 percent. And, in fact, with NDEA metabolism, 7 it gets even more complicated. Ethyl is 8 about four or five adducts. 9 So measuring the endogenous level 10 of NDMA is different from measuring the 04:08 PM 11 endogenous level of an O-6-methyl adduct. 12 Q. The O-6-methyl adduct can be 13 quantifiably measured, correct? 14 A. Correct. 15 Q. And the N7 is not the carcinogenic 04:08 PM 16 mutation that's caused by NDMA, right? 17 MR. NIGH: Form objection. 18 A. There is papers that show that N7 19 can contribute to the cancer-causing 20 activity. 04:08 PM 21 BY MR. FOWLER: 22 Q. Are you certain? 23 MR. NIGH: Form objection. 24 A. So -- well, part of the mechanism, 25 there are papers that say that you have both 04:09 PM</p>

<p style="text-align: right;">Page 266</p> <p>1 N7 and O-6 adducts as part of the --</p> <p>2 Q. Yes, sir.</p> <p>3 A. -- cancer-causing activity.</p> <p>4 I would have to see a paper that</p> <p>5 clearly showed that O-6 was the only cause of 04:09 PM</p> <p>6 NDMA-induced cancer. That's highly not</p> <p>7 likely, because to do that experiment, you</p> <p>8 would have to neutralize the O-6 metabolite</p> <p>9 and show in a knockout mouse or a</p> <p>10 neutralizing antibody that that's the key 04:09 PM</p> <p>11 cause of the cancer. So likely there's more</p> <p>12 than one adduct that causes NDMA-induced</p> <p>13 cancer.</p> <p>14 Q. Yes. Okay. That's fine, sir.</p> <p>15 But my question is, the mg O-6 04:09 PM</p> <p>16 adduct, there's no question in your mind that</p> <p>17 that is formed by NDMA metabolism, correct?</p> <p>18 MR. NIGH: Form objection.</p> <p>19 A. Yes.</p> <p>20 BY MR. FOWLER: 04:09 PM</p> <p>21 Q. Okay. And what else that you're</p> <p>22 aware of forms the O-6 mg adduct?</p> <p>23 A. So I would have to look at --</p> <p>24 there are other carcinogens, I don't know off</p> <p>25 the top of my head which ones, but that's a 04:10 PM</p>	<p style="text-align: right;">Page 268</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. And, Doctor, FDA says -- well, we</p> <p>3 covered what FDA said about the adduct.</p> <p>4 Never mind?</p> <p>5 Doctor, you know, as an expert I 04:11 PM</p> <p>6 can ask you a hypothetical. Okay?</p> <p>7 I want you to assume that there</p> <p>8 are 600 O-6 mg adducts in a human liver cell</p> <p>9 without any additional exogenous exposure.</p> <p>10 Okay? 04:12 PM</p> <p>11 With that assumption, what else</p> <p>12 would you attribute to the O-6 mg adducts</p> <p>13 other than the presence of endogenously</p> <p>14 produced NDMA?</p> <p>15 MR. NIGH: Form objection. 04:12 PM</p> <p>16 A. So the DNA adducts in this</p> <p>17 hypothetical thing, can result from other</p> <p>18 processes besides NDMA.</p> <p>19 Q. Other carcinogens or other</p> <p>20 genotoxic compounds? 04:12 PM</p> <p>21 A. Yes. Anything that induces DNA</p> <p>22 damage is genotoxic, can, in theory, mute --</p> <p>23 there's four DNA bases. So that -- you're</p> <p>24 question is with O-6. So there are other</p> <p>25 genotoxic agents that could also cause that 04:12 PM</p>
<p style="text-align: right;">Page 267</p> <p>1 general process. The formation of DNA</p> <p>2 adducts isn't specific to NDMA. The</p> <p>3 formation adducts, other carcinogens can do</p> <p>4 that.</p> <p>5 Q. Other carcinogens form the O-6 mg? 04:10 PM</p> <p>6 MR. NIGH: Form objection.</p> <p>7 A. Like I said, it's not -- I would</p> <p>8 have to look. I don't think it's specific to</p> <p>9 NDMA. To say that a biomarker -- it's very</p> <p>10 few times in cancer that you have a specific 04:10 PM</p> <p>11 biomarker to one particular chemical. It's</p> <p>12 usually a general process of cancer, in this</p> <p>13 case, initiation of cancer with the</p> <p>14 O-6-methylguanine.</p> <p>15 BY MR. FOWLER: 04:11 PM</p> <p>16 Q. Doctor, the paper that we just</p> <p>17 looked at by Dr. Kyrtopoulos stated that the</p> <p>18 presence of the O-6 mg is attributable --</p> <p>19 most likely attributable to the NDMA from</p> <p>20 endogenous sources. And I thought you agreed 04:11 PM</p> <p>21 with that?</p> <p>22 MR. NIGH: Form objection.</p> <p>23 A. No, I didn't. I said to do that</p> <p>24 experiment they give NDMA exogenously and</p> <p>25 then they look at O-6-methylguanine. 04:11 PM</p>	<p style="text-align: right;">Page 269</p> <p>1 type of adduct.</p> <p>2 Q. Okay. And, Doctor, if -- do we</p> <p>3 agree that one O-6 mg adduct is formed for</p> <p>4 one DNA molecule, correct?</p> <p>5 MR. NIGH: Form objection. 04:13 PM</p> <p>6 A. I would have to see the experiment</p> <p>7 again. In science we don't assume things. I</p> <p>8 would have to see the ratio and these are</p> <p>9 technically challenging experiments, because</p> <p>10 of these ions that are formed are very quick 04:13 PM</p> <p>11 acting, very tough to measure.</p> <p>12 Q. Yes, sir.</p> <p>13 A. But in theory you would have a</p> <p>14 certain number -- ratio of the NDMA to the</p> <p>15 adduct. 04:13 PM</p> <p>16 Is that your question?</p> <p>17 Q. It is. And it's the metabolized</p> <p>18 form of NDMA that causes the O-6 adduct,</p> <p>19 correct?</p> <p>20 A. Correct. 04:13 PM</p> <p>21 Q. And it's not your testimony, is</p> <p>22 it, sir, that one metabolized NDMA molecule</p> <p>23 could form multiple CG/AT mutations, is it?</p> <p>24 A. So what happens is that DNA adduct</p> <p>25 initiates the cancer process locally in that 04:14 PM</p>

<p style="text-align: right;">Page 270</p> <p>1 tissue, but then -- this can cause mutations. 2 So I talk about the 9 key characteristics. 3 It's a domino effect. So that -- when the 4 adduct has now targeted that tissue, by the 5 cytochrome P450s, will generate these DNA 04:14 PM 6 adducts, and what will happen is that initial 7 part of the DNA damage may be the initiation 8 of cancer, but what we now know in cancer, 9 there's multiple processes that cause that 10 cancer, not just the DNA adduct. 04:14 PM 11 So we have -- like I mentioned, 12 there's mutagens, there's impaired DNA 13 repair, genomic instability, there's 14 oxidative stress, immunosuppression. So all 15 of these process -- because the DNA is not 04:15 PM 16 the only cell in the tissue that's important. 17 You have blood vessels that stimulate 18 angiogenesis. You have immune cells that are 19 also working in direct contact with the DNA. 20 So the DNA adduct alone is not the 04:15 PM 21 only part of the causation of NDMA. That's 22 why, in my report, I focused in on 9 key 23 characteristics. And that's where, like I 24 said, IARC in the last eight years has 25 switched carcino- -- the mechanism of action 04:15 PM</p>	<p style="text-align: right;">Page 272</p> <p>1 BY MR. FOWLER: 2 Q. I'm focusing now, and we're going 3 to get to your one molecule theory. So I'm 4 trying -- I'm asking one molecule question. 5 Again, can one molecule of NDMA, 04:17 PM 6 when it's metabolized by the CYP 450 2E1, can 7 that form more than one mutation per 8 molecule? 9 MR. NIGH: Form objection. 10 A. In theory, yes. 04:17 PM 11 BY MR. FOWLER: 12 Q. What is left to act on the DNA 13 after the metabolite is used to miscode the 14 CG/AT transcription? 15 A. So this whole process, it 04:17 PM 16 initiates, like I said, a domino effect. 17 That initial one molecule that could induce 18 the DNA damage that can cause a mutation, 19 it's a domino effect. So initially there was 20 one molecule. 04:18 PM 21 But that's why a genotoxic 22 carcinogen is very dangerous, because one 23 molecule can induce DNA damage. And in 24 cancer, once you start that process, that 25 can -- you initiate these other 9 key 04:18 PM</p>
<p style="text-align: right;">Page 271</p> <p>1 of carcinogens has focused on these 10 key 2 characteristics. 3 MR. FOWLER: Madam court reporter, 4 will you please read my question back? 5 THE REPORTER: "And it's not your 04:13 PM 6 testimony, is it, sir, that one 7 metabolized NDMA molecule could form 8 multiple CG/AT mutations, is it?" 9 THE WITNESS: What was the 10 question? 04:16 PM 11 MR. FOWLER: One more time, 12 please. 13 THE REPORTER: "And it's not your 14 testimony, is it, sir, that one 15 metabolized NDMA molecule could form 04:13 PM 16 multiple CG/AT mutations, is it?" 17 THE WITNESS: So a geno- -- yes, 18 in a one molecule that's genotoxic can 19 induce -- start DNA, and there's four 20 basis of DNA. 04:17 PM 21 So the two -- like I mentioned, 22 the two most common adducts that are 23 formed, 65 percent is N7 and around 7 24 percent is the O-6. So those are the 25 two most common adducts formed. 04:17 PM</p>	<p style="text-align: right;">Page 273</p> <p>1 characteristics. 2 Q. The DNA damage caused by the NDMA 3 metabolite is a CG to AT transcription error, 4 correct? 5 A. Correct. 04:18 PM 6 Q. And that results in what is 7 referred to as the O-6 mg DNA adduct, 8 correct? 9 A. Right. 10 Q. And my question is simply this: 04:18 PM 11 Can the one molecule cause more than one 12 O-6 mg adduct or do you know? 13 MR. NIGH: Form objection. 14 A. Okay. So it's likely it forms one 15 molecule, but with that one molecule, can 04:19 PM 16 already initiate these other processes. 17 BY MR. FOWLER: 18 Q. I understand you want to say that, 19 doctor, I get that. I'm still trying to 20 focus on the O-6 mg adduct that we're talking 04:19 PM 21 about. 22 A. Okay. 23 Q. It is not your testimony that a 24 single molecule of NDMA can form multiple 25 O-6 mg adducts, is it? 04:19 PM</p>

<p style="text-align: right;">Page 274</p> <p>1 MR. NIGH: Form objection.</p> <p>2 A. No. I'm saying it can form one</p> <p>3 molecule but that one DNA adduct can go on to</p> <p>4 initiate all these other processes.</p> <p>5 BY MR. FOWLER: 04:19 PM</p> <p>6 Q. We're not there yet, Doctor. I</p> <p>7 know you want to say that.</p> <p>8 And when the mg O-6 adducts are</p> <p>9 used as the biomarker to measure NDMA, it's</p> <p>10 being -- it's based upon one molecule, one 04:19 PM</p> <p>11 adduct, correct, sir.</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. Correct, yes.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. Okay. And in your lab, sir, you 04:19 PM</p> <p>16 do not look at DNA adducts, do you, sir?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 A. We don't study DNA adducts. Like</p> <p>19 I mentioned, we study processes related --</p> <p>20 Q. Right. 04:20 PM</p> <p>21 A. -- to DNA adducts, such as</p> <p>22 oxidative stress, inflammation. Like I</p> <p>23 mentioned before, DNA damage leads to -- this</p> <p>24 oxidative DNA damage is basically key</p> <p>25 characteristic number five. There's a whole 04:20 PM</p>	<p style="text-align: right;">Page 276</p> <p>1 We agree that when we're talking</p> <p>2 one molecule of NDMA and one DNA adduct, that</p> <p>3 one DNA adduct is subject to repair by one</p> <p>4 MGMT molecule, correct.</p> <p>5 MR. FOWLER: Form objection. 04:22 PM</p> <p>6 A. Correct.</p> <p>7 BY MR. FOWLER:</p> <p>8 Q. And if that happens, that cell</p> <p>9 will not become carcinogenic, the DNA repair</p> <p>10 is efficient and stores the DNA to its 04:22 PM</p> <p>11 original integrity. Isn't that also true,</p> <p>12 sir?</p> <p>13 MR. NIGH: Form objection.</p> <p>14 A. When an adduct is formed, that's</p> <p>15 part of the process of how NDMA can initiate 04:22 PM</p> <p>16 cancer.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. Yes, sir.</p> <p>19 A. So that's how I mentioned, it's</p> <p>20 such a potent carcinogen, where even one dose 04:22 PM</p> <p>21 can initiate cancer. So that's part of --</p> <p>22 that trigger, that adduct, and that's where I</p> <p>23 have to emphasize, even though DNA repair</p> <p>24 enzymes can repair that DNA damage, it's</p> <p>25 already led to other processes that can cause 04:22 PM</p>
<p style="text-align: right;">Page 275</p> <p>1 thing on oxidative stress. And apoptotic</p> <p>2 death, hirci is part of key characteristic</p> <p>3 10, is apoptotic, cell death. They're all</p> <p>4 interlinked. That DNA damage is highly</p> <p>5 connected to what we study, which is 04:20 PM</p> <p>6 apoptotic cell death from the DNA damage.</p> <p>7 Q. The one DNA transcription error</p> <p>8 caused by one molecule of NDMA can be</p> <p>9 repaired by one molecule of MGMT; isn't that</p> <p>10 correct, sir? 04:20 PM</p> <p>11 MR. NIGH: Form objection.</p> <p>12 A. That's the function of the DNA</p> <p>13 repair enzyme.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. Yes, sir. And, in fact, when 04:21 PM</p> <p>16 we're speaking about the mg O-6 adduct that's</p> <p>17 repaired by MGMT, it's referred to as a</p> <p>18 suicide enzyme, correct, sir?</p> <p>19 A. Correct. But what I say is that</p> <p>20 NDMA can impair DNA repair enzyme. So to say 04:21 PM</p> <p>21 that NDMA induces a DNA adduct, which can be</p> <p>22 repaired by this MGMT enzyme, when we know</p> <p>23 that NDMA can also impair the enzyme.</p> <p>24 Q. I understand. I read your report,</p> <p>25 but I'm just -- baby steps. 04:21 PM</p>	<p style="text-align: right;">Page 277</p> <p>1 cancer.</p> <p>2 Q. Doctor, MGMT molecules are present</p> <p>3 in the cell, correct?</p> <p>4 A. Correct.</p> <p>5 Q. And they're present -- I want you 04:22 PM</p> <p>6 to assume they're present at a level of a</p> <p>7 thousand. If there are a thousand MGMT</p> <p>8 molecules in one cell, it can repair a</p> <p>9 thousand NDMA-induced O-6 mg adducts,</p> <p>10 correct? 04:23 PM</p> <p>11 MR. NIGH: Form objection.</p> <p>12 A. No, part of -- why that reasoning</p> <p>13 is faulty is that NDMA itself can impair NDMA</p> <p>14 repair enzymes. So what we would have to do</p> <p>15 in a study, where we would have to study that 04:23 PM</p> <p>16 exact question. And we already know that</p> <p>17 NDMA can impair this NDMA enzyme.</p> <p>18 So in a person who doesn't have</p> <p>19 NDMA, who is otherwise healthy and has an</p> <p>20 otherwise healthy MGMT DNA repair system, 04:23 PM</p> <p>21 yes, that's what the DNA repair is supposed</p> <p>22 to do; when we get DNA damage, if you go out</p> <p>23 in the sun on the beach and you get</p> <p>24 ultraviolet rays that are inducing some type</p> <p>25 of damage, the natural DNA damage that we 04:23 PM</p>

<p style="text-align: right;">Page 278</p> <p>1 get, fortunately, most of us, knock on wood, 2 don't get cancer, and that's where our 3 processes that are normally in the body are 4 working to prevent that damage. 5 And that's actually what we 04:24 PM 6 studied. The resolution of inflammation is 7 related to this debris that comes from 8 oxidative DNA damage from these adducts and 9 that we actually -- fortunately, we all have 10 in our body immune cells called macrophages 04:24 PM 11 that will clear that cell death. 12 Q. And macrophages release reactive 13 oxygen species, ROS? 14 A. They can. 15 Q. Right. 04:24 PM 16 Doctor, back to the one molecule. 17 You have no opinion, no 18 information on how long it takes a molecule 19 of MGMT to repair an O-6 mg caused by NDMA, 20 do you? 04:24 PM 21 MR. NIGH: Form objection. 22 A. So like I said NDMA can impair 23 that process. 24 BY MR. FOWLER: 25 Q. Doctor, please. 04:25 PM</p>	<p style="text-align: right;">Page 280</p> <p>1 repair enzyme. 2 But what I'm saying, is my point 3 here is that NDMA can impair that repair 4 process that we all -- normally the DNA 5 repair enzymes should repair that adduct. 04:26 PM 6 Q. There is no peer-reviewed article 7 that conclusively says, in human beings, NDMA 8 interferes with the DNA repair process, is 9 there, Doctor? 10 MR. NIGH: Form objection. 04:26 PM 11 Q. And I'll wait as long as you would 12 like to point out that article, if you have 13 it, please. 14 MR. NIGH: Form objection. 15 A. So NDMA can affect the MGMT 04:26 PM 16 process. I cited in my report that that 17 process of oxidative of genomic instability 18 and DNA -- 19 THE REPORTER: Of what 20 instability? 04:26 PM 21 THE WITNESS: Genomic instability. 22 That's key characteristics number 3. We 23 can go to that -- 24 BY MR. FOWLER: 25 Q. I don't know where you're going, 04:26 PM</p>
<p style="text-align: right;">Page 279</p> <p>1 MR. NIGH: Don't interrupt him. 2 And the other thing is, you're not on 3 video right now, and you are shaking 4 your head, you're closing your eyes, 5 you're doing all sort of things that are 04:25 PM 6 actually, I think, disruptive to the 7 expert here. It's very troubling at 8 this point. 9 MR. FOWLER: I'm sorry you're 10 troubled. 04:25 PM 11 MR. NIGH: You have to let him 12 answer the question. It may not be the 13 answer that you're seeking but 14 oftentimes you hear it in the question. 15 You're just turning it off because 04:25 PM 16 you're shaking your head, you're getting 17 frustrated. It's not okay. 18 Go ahead, if you can answer. 19 A. Well, I think part of the thing, 20 this is a hypothetical question with one 04:25 PM 21 molecule to one molecule to one molecule, and 22 that's -- in the experiments we do in 23 sentence, it's very hard to do an experiment 24 with one molecule of NDMA, with one molecule 25 of an adduct, with one molecule of a DNA 04:25 PM</p>	<p style="text-align: right;">Page 281</p> <p>1 Doctor, but I've not asked -- unless you're 2 showing me an article that says in humans 3 NDMA interferes with the DNA repair process, 4 then that's the only question that's on the 5 table right now. 04:27 PM 6 MR. NIGH: Form objection. 7 A. I didn't understand you asked in 8 in humans. 9 Q. Yes, sir. 10 THE REPORTER: Hold on, gentlemen, 04:27 PM 11 one at a time. Okay. What did you say, 12 I didn't -- 13 THE WITNESS: I didn't realize the 14 questions was in humans. Because it's 15 ethically not possible to do an 04:27 PM 16 experiment with NDMA like this, where we 17 would see the effect of NDMA on the 18 repair enzymes, many of these studies 19 have to be done in animal models or with 20 human tissue. 04:27 PM 21 So this paper I cited in my report 22 was in an animal model where the NDMA 23 impaired the DNA repair process. 24 BY MR. FOWLER: 25 Q. Doctor, from a qualitative 04:27 PM</p>

<p style="text-align: right;">Page 282</p> <p>1 standpoint, do you understand what the DNA 2 repair process is for NDMA induced O-6 mgs? 3 A. Yes. 4 MR. NIGH: Form objection. 5 A. So there's an O-6 MGMT. It's a 04:28 PM 6 methylguanine methyltransferase. That's the 7 enzyme that will repair the O-6 DNA adduct. 8 Q. Okay. And following on that 9 answer, do you understand whether it will 10 repair one or more O-6 mg adducts? 04:28 PM 11 MR. NIGH: Form objection. 12 BY MR. FOWLER: 13 Q. One molecule. 14 A. Is your question somebody exposed 15 to NDMA or just somebody -- 04:28 PM 16 Q. No. I'm saying based on your 17 study of the mechanisms and your purported 18 understanding of the DNA repair process, is 19 it one molecule of MGMT that repairs the 20 O-6 mg or does it take multiple? I don't 04:28 PM 21 know. What's your answer? 22 A. Likely it's multiple molecules -- 23 MR. NIGH: Form Objection. 24 A. -- because the studies, that's 25 where -- it's hard to do a study with just 04:28 PM</p>	<p style="text-align: right;">Page 284</p> <p>1 right? 2 A. Correct. 3 Q. And what level in the human body 4 can the MGMT not keep up with a level of 5 NDMA? 04:30 PM 6 A. So this is where we extrapolate -- 7 we cannot do that experiment in humans, 8 because NDMA is a, you know, a human 9 carcinogen. It would be unethical to do this 10 experiment in humans. 04:30 PM 11 So when that happens, the study 12 mechanism of action, routinely scientists 13 have to do this in some type of other 14 setting. Because no IRB in the world will 15 allow you to give a human carcinogen to a 04:30 PM 16 person. In fact -- so in science you have to 17 go to a different model. We do either an 18 in vivo animal model or in vitro model, and 19 that's where scientists have looked at that 20 question. 04:30 PM 21 Q. Do you know what the expert 22 panelists at the FDA nitrosamine meeting 23 concluded as to whether or not the MGMT can 24 be depleted to exposure by NDMA? Do you 25 recall what they said? 04:31 PM</p>
<p style="text-align: right;">Page 283</p> <p>1 one molecule. But they can -- there are 2 studies showing that the O-6 MGMT, the 3 methylguanine methyltransferase, that's one of 4 its function, is to repair an DNA adduct such 5 as O-6. 04:29 PM 6 But in the case of NDMA-induced 7 cancer, that process is messed up. You have 8 more O-6-methylguanine, you have impaired 9 MGMT -- or you can have the MGMT but you have 10 must have more adducts that the enzyme system 04:29 PM 11 can't repair. So that's how cancer starts, 12 that you can get the DNA damage that will 13 cause a mutation, because the repair enzyme 14 can't overcome the DNA damage from the NDMA. 15 BY MR. FOWLER: 04:29 PM 16 Q. What is your evidence of any level 17 of NDMA that the body's DNA repair process 18 can't keep up with? 19 MR. NIGH: Form objection. 20 A. So that's in the animal 04:29 PM 21 experiments that I cited; that NDMA can 22 impair that DNA repair system. 23 BY MR. FOWLER: 24 Q. You just said that the MGMT cannot 25 keep up. I believe those are your words, 04:30 PM</p>	<p style="text-align: right;">Page 285</p> <p>1 MR. NIGH: Form objection. 2 A. No. 3 MR. FOWLER: Beg the court's 4 indulgence. 5 MR. NIGH: I'm sorry, did you say 04:33 PM 6 "Beg the court's indulgence"? 7 MR. FOWLER: Well, I'm sitting 8 here not asking a question. I learned 9 that from my boss years ago, when you're 10 sitting there trying to find the page. 04:33 PM 11 Give me a second here. 12 BY MR. FOWLER: 13 Q. Let me ask it this way, Doctor, 14 and I'll come back to it if I need to. 15 If FDA and their panel of experts 04:33 PM 16 concluded that MGMT would not be depleted by 17 the presence of the NDMA, do you disagree 18 with that? Do you have any reason to 19 disagree with that? 20 MR. NIGH: Form objection. 04:33 PM 21 A. Can you just show me what they 22 said, just so I know -- 23 BY MR. FOWLER: 24 Q. I appreciate that. I understand. 25 A. Just so we're on the same page. 04:34 PM</p>

<p style="text-align: right;">Page 286</p> <p>1 Q. Absolutely. You're a good witness 2 to say that. Bear with me. 3 Thank you. Doctor, directing your 4 attention in the FDA summary that's been 5 previously marked, page 6. I appreciate your 04:34 PM 6 patience on this. 7 A. Thank you. 8 Q. In the first paragraph at the end 9 it says "The MGMT content primary human 10 tissue is at least one order of magnitude 04:35 PM 11 higher than the highest adduct level in human 12 blood DNA; therefore loss of DNA repair as a 13 result of MGMT depletion is unlikely to occur 14 at background nitrosamine exposure levels, 15 exogenous and endogenous." 04:35 PM 16 MR. NIGH: Form objection. 17 BY MR. FOWLER: 18 Q. Do you have any reason to disagree 19 what that statement, sir? 20 MR. NIGH: Form objection. 04:35 PM 21 A. That's fine. 22 BY MR. FOWLER: 23 Q. Okay. Doctor, I want you to 24 assume that a study has shown that as many as 25 100,000 MGMT molecules are present in any 04:36 PM</p>	<p style="text-align: right;">Page 288</p> <p>1 So it's not -- so the answer to 2 your question is that an NDMA-induced cancer 3 could still occur even if you have an intact 4 MGMT system. 5 BY MR. FOWLER: 04:37 PM 6 Q. Yes, sir. Doctor, out of all of 7 the 583 articles that describe the carci- -- 8 of the 583 articles that describe the 9 carcinogenicity of NDMA in animals, not a 10 single one of those studies describes 04:38 PM 11 carcinogenicity as a result of anything other 12 than the mutated NDMA -- the mutated DNA; 13 isn't that correct, sir? 14 MR. NIGH: Form objection. 15 A. No. So mutagenic DNA is one part 04:38 PM 16 of the cancer process. I wrote in the report 17 that it used to be thought there was 18 genotoxic and nongenotoxic compounds, and 19 that if you just induce DNA damage, you get 20 the cancer. 04:38 PM 21 We know today that's not right. 22 And that's why IARC has done these 10 key 23 characteristics, that the induction -- when 24 the NDMA generates this methyl diazonium ion 25 and it -- in the target tissue causes the 04:38 PM</p>
<p style="text-align: right;">Page 287</p> <p>1 given cell. 2 With that in mind, Doctor, do you 3 have any reason to believe that the MGMT 4 could not keep up with the incremental 5 increase of exogenous exposure of NDMA 04:36 PM 6 contained in the valsartan tablets? 7 MR. NIGH: Form objection. 8 A. So, as mentioned in my report, 9 there's multiple mechanisms of action for 10 NDMA. Inducing the DNA adduct is only one of 04:36 PM 11 9 key characteristics; and, in fact, it's 12 part of one process, and key characteristics, 13 potent electrophiles. There's other 14 mechanisms where NDMA can cause cancer. 15 So even if the MGMT was able to, 04:36 PM 16 in this hypothetical that you're saying with 17 100,000 molecules, was able to keep up with 18 the DNA adduct from NDMA, NDMA is doing other 19 processes, such as the genotoxicity, the 20 mutagenicity, the oxidative stress, the -- in 04:37 PM 21 stimulating inflammation, stimulating 22 chronic -- immunosuppressive, inducing cell 23 death, stimulating angiogenesis. So all of 24 these process work together to cause the 25 cancer. 04:37 PM</p>	<p style="text-align: right;">Page 289</p> <p>1 cancer, all of these processes are going on. 2 So it's not just the one genotoxic DNA adduct 3 process. 4 There's impaired -- there's 5 genomic instability, like I mentioned; 04:39 PM 6 there's oxidative stress, an angiogenesis, 7 formation of new blood vessels, increased 8 proliferation. NDMA stimulates 9 proliferation. That's why I detailed in my 10 report the 9 out of 10 key characteristics 04:39 PM 11 that NDMA can use as a mechanism to cause the 12 cancer. 13 MR. NIGH: Mr. Fowler, It's been 14 more than an hour since our last break. 15 How much longer do you think you have? 04:39 PM 16 MR. FOWLER: How much longer 17 before the next break? 18 MR. NIGH: Before the next break, 19 right. 20 MR. FOWLER: Personally I would 04:39 PM 21 just keep going. So I don't -- I 22 wouldn't be thinking break, but since 23 you've called it to our attention, and 24 we've now stopped the deposition, we'll 25 take a break. So that's fine. Just let 04:39 PM</p>

<p style="text-align: right;">Page 290</p> <p>1 me know when you want one, and, 2 obviously, we can take one. Go ahead. 3 Take whatever you need. Five, ten 4 minutes sir? I don't care. 5 THE VIDEOGRAPHER: The time is 04:40 PM 6 4:39. 7 (Recess taken at 4:39 p.m. to 4:53 p.m.) 8 THE VIDEOGRAPHER: The time is 9 4:53. We're back on the record. 10 BY MR. FOWLER: 04:54 PM 11 Q. Okay. Dr. Panigrahy, let me just 12 kind of wrap up this discussion about the 13 endogenous NDMA. 14 And let me direct your attention 15 to page 27 again of the FDA summary. 04:54 PM 16 And in the middle of the third 17 paragraph, the one that starts the DNA 18 adducts -- 19 MR. FOWLER: Holy moly. 20 MR. NIGH: Somebody is making a 04:54 PM 21 lot of noise on the Zoom. 22 MR. FOWLER: I hear a child. 23 BY MR. FOWLER: 24 Q. Doctor, at the bottom of that 25 paragraph, that third paragraph down, it 04:55 PM</p>	<p style="text-align: right;">Page 292</p> <p>1 much to the overall risks. However, this is 2 unknown at present." 3 Do you agree with that, Doctor? 4 A. No, I don't agree. 5 First of all, this FDA document, 04:56 PM 6 what I'm seeing, is a workshop. It's not a 7 peer-reviewed publication. It's not an 8 official release from the FDA. It's a 9 workshop. And I've attended workshops like 10 this. I wasn't at this particular one, where 04:56 PM 11 scientists present their cutting edge 12 research, but regulatory agencies have to 13 decide on what's known at the time. 14 And one thing we do stress is in 15 peer-reviewed papers and publications. In 04:57 PM 16 fact, what we were talking to when I went on 17 page 5, what we were talking about, the MGMT, 18 the second sentence is, "However, this is 19 controversial because of the uncertainty over 20 repair capacity." 04:57 PM 21 So these workshops are very 22 helpful, in that scientists will present 23 their cutting edge research. But for a 24 statement like "the amount in drugs may not 25 add much to overall risk; however, this is 04:57 PM</p>
<p style="text-align: right;">Page 291</p> <p>1 states, "Ultimately, the amount in drugs may 2 not add much to the overall risk. However, 3 this is unknown at present." 4 MR. FOWLER: Whoever is on -- 5 somebody needs to mute, please. 04:55 PM 6 MS. BOGDAN: Whoever is running 7 the Zoom, mute. 8 MR. NIGH: Do we have somebody 9 running the Zoom? Do we have the 10 capability of muting them? 04:55 PM 11 MS. BOGDAN: Somebody is running 12 the Zoom. 13 MR. FOWLER: I can't even control 14 the remote to the TV. Okay. That's 15 better. 04:55 PM 16 BY MR. FOWLER: 17 Q. Let me start the question again, 18 Doctor. 19 Understanding that you are unable 20 to quantify -- or agree on a quantified level 04:56 PM 21 of endogenously produced NDMA and FDA also 22 agreed that a direct quantification is 23 challenging, FDA says, with that in mind, at 24 the bottom of that paragraph, on 27, 25 "Ultimately, the amount in drugs may not add 04:56 PM</p>	<p style="text-align: right;">Page 293</p> <p>1 unknown at present," I base my report on over 2 hundreds of publications, many in 3 peer-reviewed publications, and I based my 4 opinion that NDMA and NDEA are human 5 carcinogens and can cause cancer, also guided 04:57 PM 6 by the most recent six reports from the 7 public agencies, including IARC, EPA, NTP, 8 DHS, EMA and Canada. 9 So I don't agree with that 10 sentence. 04:58 PM 11 Q. Do you disagree that FDA impeaneled 12 experts in various areas, including 13 genotoxicity, oncology, toxicology? We could 14 go through the list. Do you disagree that 15 these are expert panelists that they brought 04:58 PM 16 together? 17 MR. NIGH: Form objection. 18 A. No. That's part of what I'm 19 saying, with science, you need to bring 20 together experts in a field and these 04:58 PM 21 particular experts are presenting their 22 cutting edge, their own science. 23 But when we determine -- when I 24 determine an opinion on whether NDMA or NDEA 25 causes human cancer -- when NDMA and NDEA in 04:59 PM</p>

<p style="text-align: right;">Page 294</p> <p>1 a contaminated valsartan tablet causes --</p> <p>2 THE REPORTER: I'm sorry, when</p> <p>3 NDMA?</p> <p>4 THE WITNESS: And NDEA.</p> <p>5 THE REPORTER: Yep. "Causes"? 04:59 PM</p> <p>6 THE WITNESS: -- human cancer, I</p> <p>7 have to rely heavily on peer-reviewed</p> <p>8 publications; and, like I said, the four</p> <p>9 different processes that we went through</p> <p>10 with animal studies, animal mechanism, 04:59 PM</p> <p>11 human mechanism, epi studies.</p> <p>12 So I rely on that. And then also,</p> <p>13 on what the FDA's suggestion is, and as</p> <p>14 far as -- and then other agencies too.</p> <p>15 And as I said before, all the agencies 04:59 PM</p> <p>16 have either said that NDMA or NDEA are</p> <p>17 probable human carcinogens or reasonably</p> <p>18 expected to be a human carcinogen.</p> <p>19 BY MR. FOWLER:</p> <p>20 Q. Why didn't you take your time to 04:59 PM</p> <p>21 attend or watch or read anything about FDA's</p> <p>22 workshop on nitrosamines, talking about the</p> <p>23 valsartan drug with the levels of NDMA in it?</p> <p>24 Why didn't you pay attention to that, sir?</p> <p>25 MR. NIGH: Form objection. 05:00 PM</p>	<p style="text-align: right;">Page 296</p> <p>1 MR. NIGH: Go ahead. You can</p> <p>2 answer.</p> <p>3 BY MR. FOWLER:</p> <p>4 Q. Do you put any value to the expert</p> <p>5 panelists' conclusions that are expressed in 05:01 PM</p> <p>6 this summary, Doctor? Do you give any value</p> <p>7 to that?</p> <p>8 A. Like I said, in science, I will</p> <p>9 consider all the evidence and all the data,</p> <p>10 but one thing that we as scientists are 05:01 PM</p> <p>11 critical about is peer-reviewed publications.</p> <p>12 And this particular workshop, I would have to</p> <p>13 see if they had a consensus statement at the</p> <p>14 end.</p> <p>15 Q. Let me direct your attention to 05:01 PM</p> <p>16 page 5. Let's see if we can explore one of</p> <p>17 those. Top of page 5, sir.</p> <p>18 "The expert panelists emphasized</p> <p>19 the importance of determining endogenous</p> <p>20 formation for assessing risk and recommended 05:02 PM</p> <p>21 that experimental work be initiated as soon</p> <p>22 as possible."</p> <p>23 Do you agree with that statement?</p> <p>24 A. And I agree with that statement.</p> <p>25 That's what I previously said; that in 05:02 PM</p>
<p style="text-align: right;">Page 295</p> <p>1 A. So I was not aware of this</p> <p>2 conference on March 29th to 30th. I have --</p> <p>3 part of what I do is, as the process of</p> <p>4 determining an opinion, is going through,</p> <p>5 like I said, the peer-reviewed process. So I 05:00 PM</p> <p>6 wasn't part of this workshop.</p> <p>7 There are literally hundreds of</p> <p>8 workshops that scientists attend to, and I've</p> <p>9 been parts of other workshops, and I wasn't</p> <p>10 part of this workshop. 05:00 PM</p> <p>11 BY MR. FOWLER:</p> <p>12 Q. It was open to the public, right?</p> <p>13 I mean, I attended. Strike that.</p> <p>14 Doctor, do you put any -- do you</p> <p>15 give any value to a consensus that was formed 05:00 PM</p> <p>16 by the panel of 14 experts that FDA brought</p> <p>17 together to discuss the very same issue that</p> <p>18 we're here about today?</p> <p>19 MR. NIGH: Hold on. Form</p> <p>20 objection. There was no consensus. 05:01 PM</p> <p>21 THE WITNESS: I would have to</p> <p>22 see the --</p> <p>23 MR. NIGH: You were there at the</p> <p>24 workshop.</p> <p>25 MR. FOWLER: Counsel, I -- 05:01 PM</p>	<p style="text-align: right;">Page 297</p> <p>1 science, we have questions that are</p> <p>2 unanswered and it takes time to answer them.</p> <p>3 But public regulatory agencies,</p> <p>4 like FDA, can't wait on data until it comes</p> <p>5 out in the public, either peer-reviewed paper 05:02 PM</p> <p>6 or some type of -- or they take part in, like</p> <p>7 an IARC monograph, IARC has 120 monographs</p> <p>8 that the FDA and 24 countries worldwide use</p> <p>9 those 120 IARC monographs to determine</p> <p>10 whether -- to determine risk -- you know, for 05:02 PM</p> <p>11 risk for assessment.</p> <p>12 In this case -- it is very</p> <p>13 important to do workshops such as this. And</p> <p>14 this is a very important question about</p> <p>15 endogenous formation; but currently, as of 05:03 PM</p> <p>16 today, we don't have a reliable method to</p> <p>17 quantify the endogenous amount of NDMA in the</p> <p>18 body.</p> <p>19 Q. And so you didn't consider it in</p> <p>20 making your own risk assessment. Isn't that 05:03 PM</p> <p>21 true, Doctor?</p> <p>22 MR. NIGH: Form objection.</p> <p>23 A. I didn't -- what was the question?</p> <p>24 BY MR. FOWLER:</p> <p>25 Q. You didn't consider any level of 05:03 PM</p>

75 (Pages 294 - 297)

<p style="text-align: right;">Page 298</p> <p>1 endogenous production in your own risk 2 assessment in this case, did you, sir? 3 MR. NIGH: Form objection. 4 A. No, I did -- I cited some papers 5 that talk about endogenous NDMA; and as I 05:03 PM 6 said before, as of this time, where there's 7 no accurate biological way to measure 8 endogenous NDMA and the question was does 9 exogenous NDMA in a contaminated valsartan 10 pill cause human cancer. So I focused on the 05:03 PM 11 exogenous mechanisms of NDMA. 12 But just because in science you 13 can't detect something or something is not 14 possible yet, that doesn't mean you don't 15 consider it. 05:04 PM 16 Q. You just said you considered the 17 endogenous mechanisms of NDMA? 18 A. I meant -- sorry. I mean to say 19 the exogenous administration of NDMA in the 20 valsartan tablet. 05:04 PM 21 Q. Thank you. Directing your 22 attention to page 7, third line down, "The 23 expert panelists agreed that exposure from 24 endogenous formation of nitrosamines is 25 likely to be higher than exposure from 05:04 PM</p>	<p style="text-align: right;">Page 300</p> <p>1 BY MR. FOWLER: 2 Q. So, Doctor, then, to be clear and 3 to be fair to this panel, you have no 4 information one way or the other -- let me 5 start that again. 05:06 PM 6 To be fair to this panel, you 7 cannot say that the science they presented 8 was, quote/unquote, "cutting edge," because 9 you don't know what they presented. Isn't 10 that true? 05:06 PM 11 MR. NIGH: Form objection. 12 A. Correct. 13 BY MR. FOWLER: 14 Q. Thank you. 15 A. My statement was, in general, 05:06 PM 16 workshops, such as the different Gordon 17 conferences, these are workshops where 18 scientists get together and will present 19 unpublished data and brainstorm and try to 20 answer different questions. 05:06 PM 21 Q. And, Doctor, I noticed in your 22 report that you contend, on page 216, that 23 NDMA and NDEA are synergistic. 24 Do you recall making a statement 25 like that in your report? 05:06 PM</p>
<p style="text-align: right;">Page 299</p> <p>1 exogenous sources such as food." 2 Do you have any reason to disagree 3 with this statement that the expert panelists 4 agreed to in this case? 5 A. Like I said, this is -- I would 05:05 PM 6 have to see the data to support that 7 statement. Taking -- this isn't even a 8 peer-reviewed publication. So I would have 9 to see what the evidence for that statement 10 is before I... 05:05 PM 11 Q. And where do you get the notion 12 that these esteemed scientists that FDA 13 impaneled were presenting, quote/unquote, 14 "cutting edge science"? Where do you get 15 that from, sir? 05:05 PM 16 MR. NIGH: Hold on. Form 17 objection. You can answer. 18 A. That's meant more in general. I 19 wasn't at this workshop. So I would have to 20 see what they presented. 05:05 PM 21 In general, the workshops like 22 this are so scientists can present their most 23 recent data, and so the idea is to come to 24 help common -- important questions. 25 / 05:05 PM</p>	<p style="text-align: right;">Page 301</p> <p>1 A. Yes. 2 Q. Now, let me direct your attention 3 to page 27 of the FDA summary. Second 4 paragraph, "When more than one nitrosamine is 5 found in a drug, the expert panelists agreed 05:07 PM 6 that their effects would be additive." 7 Do you see that, sir? 8 A. Yes. 9 Q. Are you aware that Plaintiffs' own 10 expert, Dr. Stephen Hecht, said, 05:07 PM 11 unequivocally, that the effects would be 12 additive, between NDMA and NDEA? 13 MR. NIGH: Form objection. 14 BY MR. FOWLER: 15 Q. Were you aware of that, sir? 05:07 PM 16 MR. NIGH: Form objection. 17 A. No, I was not aware aware of that. 18 BY MR. FOWLER: 19 Q. You were not aware that Dr. Hecht 20 testified both before the FDA and before this 05:07 PM 21 court that it's his opinion that NDMA and 22 NDEA are additive and not synergistic? Were 23 you made aware of that? 24 MR. NIGH: Form objection. 25 A. So when I -- yeah, I relied on 05:08 PM</p>

<p style="text-align: right;">Page 302</p> <p>1 papers showing that nitrosamines together, 2 this study here, investigated the potential 3 synergistic cancer-causing activity of more 4 than one nitrosamine and add the carcinogenic 5 effects of very low-dose nitrosamines, 05:08 PM 6 including NDEA. 7 Q. So are you disagreeing with 8 Plaintiffs' own expert that NDMA and NDEA 9 is -- you're saying it's synergistic, you 10 disagree that it's additive? 05:08 PM 11 MR. NIGH: Hold on. Form 12 objection. Mischaracterizes testimony. 13 You can answer. 14 A. Yeah, to separate additive and 15 synergistic, that -- they both mean that two 05:08 PM 16 compounds together have more activity than 17 each one alone. So when I referred here that 18 NDMA and ND [sic] are synergistic in causing 19 cancer, I'm talking about that they're, in 20 effect, they're more potent than either one 05:09 PM 21 alone. 22 BY MR. FOWLER: 23 Q. Well, Doctor, synergistic and 24 additives are two separate concepts, correct? 25 MR. NIGH: Form objection. 05:09 PM</p>	<p style="text-align: right;">Page 304</p> <p>1 Q. Strike that. 2 Do you now accept that NDMA and 3 NDEA will be additive if they're found in the 4 body together? Do you want to walk back the 5 notion of synergy, sir? 05:10 PM 6 MR. NIGH: Form objection. 7 A. I think the important thing here 8 is that the cancer-causing activity of each 9 one gets worse when you put it together. 10 If you want -- in science, if you 05:10 PM 11 want to dive into the technical details of 12 the difference between addition and 13 synergistic, that requires precise 14 mathematical modeling. I wasn't asked the 15 question of is NDMA and NDEA together 05:11 PM 16 additive or synergistic. To do it 17 appropriately, there's different mathematical 18 formulas and there's different experiments 19 you have to do to prove synergy versus 20 additive. 05:11 PM 21 The point in my report, was that 22 when you put each one by itself, causes 23 cancer as a potent human carcinogen, and when 24 you put them together, they can potentially, 25 and I wrote here "the potential synergistic 05:11 PM</p>
<p style="text-align: right;">Page 303</p> <p>1 BY MR. FOWLER: 2 Q. Let me try that again. Synergy 3 and additive do not mean the same thing, do 4 they? 5 A. Right. So, in my report, when 05:09 PM 6 I -- I'm compiling my context of how I wrote 7 it with 500 or 600 citations. In all the 8 animal experiments I talk about the potency 9 of each one. So I do it in the context of 10 this report. 05:09 PM 11 Q. And when Dr. Hecht was asked by 12 the panel "When one more than one 13 nitrosamines is found in a drug, the 14 panelists agreed that their effects would be 15 additive." 05:10 PM 16 Dr. Hecht says "Yes, I agree. 17 Considering the low levels that we are going 18 to be observing, additivity is definitely the 19 default assumption of the molar amounts that 20 are present. So I agree with everything 05:10 PM 21 that's been said about additivity." 22 And I refer to Day 1 transcript 23 page 143, line 15 to 19. 24 Do you disagree with that, sir? 25 A. Well -- 05:10 PM</p>	<p style="text-align: right;">Page 305</p> <p>1 cancer-causing activity." 2 So in the context of my report, 3 I'm suggesting, in my opinion, is they could 4 be synergistic. 5 BY MR. FOWLER: 05:11 PM 6 Q. Well you didn't say could be, sir. 7 If I'm looking at page 16, you state "NDMA 8 and NDEA are synergistic in causing cancer." 9 Were you using that word maybe in 10 a different way? 05:12 PM 11 MR. NIGH: Do you mean page 216? 12 MR. FOWLER: What did I say? 13 MR. NIGH: 16. 14 MR. FOWLER: Thank you, Counsel. 15 BY MR. FOWLER: 05:12 PM 16 Q. Page 216, you didn't say "could," 17 you said they are, Doctor. 18 And I'd like to ask if you want to 19 change that use of the term "synergy"? 20 MR. NIGH: Form objection. 05:12 PM 21 A. No, in the context of my report, I 22 wrote -- so the context here is potential 23 synergistic activity." 24 That means they are additive 25 already. So synergy means that they together 05:12 PM</p>

<p style="text-align: right;">Page 306</p> <p>1 are worse than each one alone and they have 2 other activities. 3 When I detail the 10 key 4 characteristics in the context of my report, 5 where each one -- NDMA exhibits 9 key 05:12 PM 6 characteristics, and NDEA is 9 key 7 characteristics, this study would support the 8 potential synergistic activity. So my 9 opinion is that these can be synergistic. 10 Q. Okay. And I can accept that, so 05:13 PM 11 now it's can be. You're not making an 12 opinion that they are? 13 MR. NIGH: Form objection. 14 BY MR. FOWLER: 15 Q. Right? 05:13 PM 16 MR. NIGH: Form objection. 17 BY MR. FOWLER: 18 Q. You're hypothesizing, Doctor, 19 right? 20 MR. NIGH: Form objection. 05:13 PM 21 A. No, I'm still saying they are 22 synergistic. 23 BY MR. FOWLER: 24 Q. Okay. Thank you. Let's move on. 25 You can set that aside. 05:13 PM</p>	<p style="text-align: right;">Page 308</p> <p>1 MR. NIGH: Form objection. 2 A. Likely it would be more than one 3 molecule, yes. 4 BY MR. FOWLER: 5 Q. And can we also agree that the 05:15 PM 6 loss of two tumor suppressor -- 7 A. Actually, I need to say. In 8 theory, a genotoxic substance, like we've 9 mentioned before, even one molecule can 10 trigger DNA damage that could trigger these 05:15 PM 11 other processes that I've talked about. 12 Q. I understand. And I've heard you 13 today on that, sir. 14 But my question right now, just 15 on this article that you cited, it requires 05:15 PM 16 activation of two oncogenes, and I think we 17 just agreed that would take more than one 18 molecule of NDMA, correct, sir? 19 MR. NIGH: Form objection. 20 A. Yes. 05:15 PM 21 BY MR. FOWLER: 22 Q. And the loss of two tumor 23 suppressor genes, like the P53, sir, to lose 24 two genes would require more than one 25 molecule of NDMA, correct? 05:15 PM</p>
<p style="text-align: right;">Page 307</p> <p>1 MR. FOWLER: I'm going to 2 introduce Exhibit 14. 3 (Exhibit 14, Genetic and Cellular Basis of 4 Multistep Carcinogenesis, marked for 5 identification.) 05:14 PM 6 BY MR. FOWLER: 7 Q. Dr. Panigrahy, Exhibit 14 is an 8 article by Dr. Jeff Boyd and J. Carl Barrett 9 from 1990, Genetic and Cellular Basis of 10 Multistep Carcinogenesis. This was cited in 05:14 PM 11 your report Footnote 47. 12 So you reviewed this article, 13 correct, sir. 14 A. Correct. 15 Q. And if we look in the abstract and 05:14 PM 16 it's talking about the Syrian hamster, it 17 says "Neoplastic progression requires four 18 heritable changes, involving activation of 19 two oncogenes and loss of two tumor 20 suppressor genes." 05:14 PM 21 Do you see that, sir? 22 A. Yes. 23 Q. Can we agree that activation of 24 two oncogenes would take more than one 25 molecule of NDMA? 05:14 PM</p>	<p style="text-align: right;">Page 309</p> <p>1 MR. NIGH: Form objection. 2 A. So while one -- in theory, one 3 molecule could cause it. Likely it would be 4 more than one molecule to affect the tumor 5 suppressor gene, so correct. 05:16 PM 6 BY MR. FOWLER: 7 Q. You can set that aside. 8 Is your theory in this case that 9 we've heard today about one molecule causing 10 cancer, is that a single exposure or a single 05:16 PM 11 hit theory of carcinogenicity, sir? 12 MR. NIGH: Form objection. 13 A. It's a single exposure. And the 14 single hit and this multistage process of 15 cancer has actually evolved now. It used to 05:16 PM 16 be thought cancer was an initiation, 17 promotion, progress; and now we know, that's 18 why when it -- also in cancer there are the 19 hallmarks of cancer, which were the classic 20 Hanahan-Weinberg 2000 cell paper, the most 05:17 PM 21 cited paper, and then the follow up was the 22 Hallmarks of Cancer: The Next Generation, 23 2011, which included genomic instability and 24 inflammation. Those are properties of how 25 cancer cells can cause cancer. 05:17 PM</p>

<p style="text-align: right;">Page 310</p> <p>1 When IARC met in 2012, they</p> <p>2 realized, as a group, that the question here</p> <p>3 is -- does a chemical cause cancer, and</p> <p>4 that's different from the progression of</p> <p>5 cancer, which used to be thinking of one hit, 05:17 PM</p> <p>6 two hit, four hits or the multistage</p> <p>7 progression.</p> <p>8 So what IARC did was go through 50</p> <p>9 different Group 1 carcinogens and say what</p> <p>10 was the mechanism that they used, which 05:17 PM</p> <p>11 hallmarks of cancer did they use, and then</p> <p>12 get into the mechanisms of cancer causation.</p> <p>13 And that's where the key characteristics are</p> <p>14 much more updated and relevant than the</p> <p>15 multistep carcinogen process of one hit or 05:18 PM</p> <p>16 two hits or four hits.</p> <p>17 So that's why now the IARC uses 10</p> <p>18 key characteristics as the mechanisms of</p> <p>19 whether a chemical can cause human cancer.</p> <p>20 BY MR. FOWLER: 05:18 PM</p> <p>21 Q. And, again, IARC is simply a</p> <p>22 hazard-identifying organization. It is not</p> <p>23 offering opinions or statements whether a</p> <p>24 carcinogen causes cancer, does it?</p> <p>25 MR. NIGH: Form objection. 05:18 PM</p>	<p style="text-align: right;">Page 312</p> <p>1 A. Correct.</p> <p>2 Q. And you did not include this in</p> <p>3 your 583 references, did you?</p> <p>4 A. Correct.</p> <p>5 Q. Okay. If we look at the abstract, 05:20 PM</p> <p>6 let's just cut to the chase and look at the</p> <p>7 last sentence, sir.</p> <p>8 "These results" -- let me start</p> <p>9 the clean question.</p> <p>10 This paper reports that -- and 05:20 PM</p> <p>11 this is a peer-reviewed paper, right, sir?</p> <p>12 A. Yes, it looks to be a</p> <p>13 peer-reviewed paper.</p> <p>14 Q. And it's written by actual</p> <p>15 pharmacologists, pathologists and 05:21 PM</p> <p>16 toxicologists, correct, sir?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 A. I can't tell from the paper -- I</p> <p>19 mean, it's from the Department of</p> <p>20 Pharmacology and Toxicology. 05:21 PM</p> <p>21 BY MR. FOWLER:</p> <p>22 Q. All right. Fair enough, sir.</p> <p>23 The study states, at the end of</p> <p>24 the abstract, "These results further support</p> <p>25 the observations of the authors that 05:21 PM</p>
<p style="text-align: right;">Page 311</p> <p>1 A. Right, and they're very clear</p> <p>2 that -- they assemble the scientists and they</p> <p>3 decide does a chemical cause cancer. And</p> <p>4 then over 24 countries in the world,</p> <p>5 including United States, Canada, the European 05:18 PM</p> <p>6 countries use these monographs as guiding</p> <p>7 them toward risk assessment.</p> <p>8 So yes, the initial hazard</p> <p>9 evaluation is done by IARC and IARC has a --</p> <p>10 their method to determine whether a chemical 05:19 PM</p> <p>11 causes cancer is very well established and</p> <p>12 that's a method that I follow too. And then</p> <p>13 the regulatory agencies will use those</p> <p>14 monographs and -- as well as other agencies,</p> <p>15 like EPA, NTP, you know, and other agencies, 05:19 PM</p> <p>16 to determine their risk assessment.</p> <p>17 MR. FOWLER: Exhibit 15, please.</p> <p>18 (Exhibit 15, Concordance of thresholds for</p> <p>19 carcinogenicity of N-nitrosodiethylamine,</p> <p>20 marked for identification.) 05:20 PM</p> <p>21 Q. Before you, Doctor, is Exhibit 15.</p> <p>22 It's a 2006 article by Dr. William Waddell,</p> <p>23 entitled "Concordance of thresholds for</p> <p>24 carcinogenicity of NDEA," correct, that's</p> <p>25 what we're looking at here? 05:20 PM</p>	<p style="text-align: right;">Page 313</p> <p>1 thresholds for carcinogenicity of this</p> <p>2 genotoxic carcinogen exist and that adducts</p> <p>3 and altered foci appear at lower doses than</p> <p>4 the threshold for carcinogenicity."</p> <p>5 Did I read that correctly? 05:22 PM</p> <p>6 A. Yes.</p> <p>7 Q. And do you understand that,</p> <p>8 according to this article, the authors found</p> <p>9 that NDEA has a carcinogenicity threshold;</p> <p>10 that's what's reported, correct, sir? 05:22 PM</p> <p>11 MR. NIGH: Form objection.</p> <p>12 A. Yes.</p> <p>13 BY MR. FOWLER:</p> <p>14 Q. And if you look to the conclusion,</p> <p>15 sir, on the -- well, at the conclusion, just 05:22 PM</p> <p>16 before the references, four pages in. The</p> <p>17 last sentence, "These results further confirm</p> <p>18 the previous findings of these authors that</p> <p>19 there is a definite threshold for</p> <p>20 preneoplastic events and also for tumor 05:22 PM</p> <p>21 formation in genotoxic carcinogens."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 MR. NIGH: Form objection.</p> <p>25 / 05:22 PM</p>

<p style="text-align: right;">Page 314</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. Do you see the table up above,</p> <p>3 that neat little graph?</p> <p>4 A. Yes.</p> <p>5 Q. And do you -- do you agree or 05:23 PM</p> <p>6 disagree that that chart, according to this</p> <p>7 data, demonstrates a level of exposure that</p> <p>8 does not increase the adducts followed by the</p> <p>9 uptick, if you will, hockey stick going up,</p> <p>10 correct, sir? 05:23 PM</p> <p>11 A. Correct.</p> <p>12 Q. And do you have any reason to</p> <p>13 dispute the findings of these scientists with</p> <p>14 their conclusion that NDEA has a definite</p> <p>15 threshold of carcinogenicity? 05:23 PM</p> <p>16 A. Yes, so --</p> <p>17 Q. Do you disagree?</p> <p>18 A. Yes, I disagree.</p> <p>19 So in science we don't</p> <p>20 determine -- I don't determine evidence based 05:23 PM</p> <p>21 on one paper. We do multiple papers,</p> <p>22 multiple science, there's multiple labs. So</p> <p>23 what this paper is assuming, that the DNA</p> <p>24 adducts correlate with the cancer causation.</p> <p>25 And now we know today, this paper is in 2006, 05:24 PM</p>	<p style="text-align: right;">Page 316</p> <p>1 1991, and then Terracini 1967, and there's</p> <p>2 other papers. And with that lin- -- what it</p> <p>3 shows is NDMA and NDEA have a linear</p> <p>4 response. And the 40 or 50 years of cancer</p> <p>5 research, overwhelming has shown that 05:25 PM</p> <p>6 genotoxic carcinogens are bad, they're</p> <p>7 dangerous, and we want to minimize exposure</p> <p>8 to them.</p> <p>9 And so the reason that -- and I</p> <p>10 agree with the FDA, the EMA, the EPA, and the 05:25 PM</p> <p>11 Canadian health agencies, that NDMA and NDEA</p> <p>12 are genotoxic, there's no threshold and</p> <p>13 there's no safe dose, and we want to minimize</p> <p>14 exposure to this carcinogen.</p> <p>15 Q. Doctor, two things. One, FDA has 05:26 PM</p> <p>16 never come out and said that there's no</p> <p>17 threshold, have they?</p> <p>18 MR. NIGH: Form objection.</p> <p>19 A. Their guidance has cited -- right,</p> <p>20 so have cited the papers saying that 05:26 PM</p> <p>21 mutagenic and genotoxic carcinogens have no</p> <p>22 threshold. And, as I said, I don't rely only</p> <p>23 on the FDA. The EMA, which in their 2020</p> <p>24 document, which is almost a hundred pages,</p> <p>25 says that NDMA and NDA [sic] do not have a 05:26 PM</p>
<p style="text-align: right;">Page 315</p> <p>1 we know today that that's not true; that</p> <p>2 that's why the ultimate test of whether a</p> <p>3 cancer caused -- whether a chemical causes</p> <p>4 cancer is a chemical carcinogenesis assay,</p> <p>5 the bioassay. You give a chemical, does it 05:24 PM</p> <p>6 cause cancer?</p> <p>7 Because there are cases where a</p> <p>8 DNA adduct, and this is a case, for example,</p> <p>9 in aflatoxin, which is a carcinogen that</p> <p>10 causes DNA adducts, and this has been shown 05:24 PM</p> <p>11 well in the peer-reviewed literature that the</p> <p>12 DNA adducts from aflatoxin do not correlate</p> <p>13 with the cancer-causing activity.</p> <p>14 And that fits what I wrote in this</p> <p>15 report, what many scientists now know, 05:24 PM</p> <p>16 that the -- what I talk about, the key</p> <p>17 characteristics of cancer causation. DNA</p> <p>18 adducts are not the only mechanism. So to</p> <p>19 determine a threshold with the -- via the</p> <p>20 adducts, it would be something I wouldn't 05:25 PM</p> <p>21 agree with.</p> <p>22 And then, like I said, I look at</p> <p>23 different papers, and the papers that I cited</p> <p>24 in my report support that the NDMA and NDEA</p> <p>25 have no threshold. And so the Peto paper, 05:25 PM</p>	<p style="text-align: right;">Page 317</p> <p>1 threshold; there's no safe dose. And they</p> <p>2 suggested minimizing exposure to NDMA and</p> <p>3 NDEA.</p> <p>4 And, like I said, the EPA has said</p> <p>5 this is a carcinogen that's multisite, 05:27 PM</p> <p>6 multispecies, causes cancer by six different</p> <p>7 methods of administration. And I know I've</p> <p>8 said this before, NDEA, which is what we're</p> <p>9 talking about in this paper, causes cancer in</p> <p>10 18 different species. It causes cancer -- 05:27 PM</p> <p>11 when you have multispecies in animal models,</p> <p>12 as I said before, Meroncot 1994, Tomatis, who</p> <p>13 was one of the key leaders in IARC over the</p> <p>14 years, abundant literature has shown, and</p> <p>15 that's how to avoid -- in the end of the day 05:27 PM</p> <p>16 we want to try to prevent cancer and help</p> <p>17 people not to have to go through the</p> <p>18 suffering.</p> <p>19 To do that, you identify human</p> <p>20 carcinogens, and to do that, the definitive 05:28 PM</p> <p>21 test is you show in animals does a chemical</p> <p>22 cause cancer; and if it does, it's a presumed</p> <p>23 human carcinogen until proven otherwise.</p> <p>24 Q. Doctor, you just testified under</p> <p>25 oath that you agree with FDA stating that 05:28 PM</p>

<p style="text-align: right;">Page 318</p> <p>1 there is a threshold, and I want to be 2 crystal clear here. 3 You can point to nothing that FDA 4 has ever published that says there's a 5 threshold, can you? 05:28 PM 6 A. I said there's no threshold. 7 Q. Thank you. FDA has never 8 published that there's no threshold. You 9 said you agree with FDA on that, and they've 10 never said that, have they, sir? 05:28 PM 11 MR. NIGH: Form objection. 12 A. Well, I should clarify. 13 BY MR. FOWLER: 14 Q. Please. 15 A. The no threshold -- so IARC and 05:28 PM 16 the EMA, in their document, the EPA, they 17 cite other papers which -- and they, in their 18 opinions, in these pieces will say that for 19 public regulation currently, they say to 20 minimize exposure to a genotoxic mutagenic 05:29 PM 21 carcinogen such as NDMA and NDEA. 22 Q. Doctor, you testified under oath 23 that FDA says there's no threshold and they 24 they've never said that; isn't that true? 25 MR. NIGH: Form objection. 05:29 PM</p>	<p style="text-align: right;">Page 320</p> <p>1 response -- on a linear curve. 2 Q. Doctor, could we please get a 3 clean answer to my question? 4 FDA has never come out with any 5 publication where FDA concludes there is no 05:30 PM 6 threshold. Yes or no, sir? 7 A. Correct. 8 Q. Thank you. And EMA and Health 9 Canada, none of those agencies have ever 10 taken -- have ever published a position that 05:31 PM 11 NDMA and NDEA have no threshold, none of the 12 agencies you just rattled off have ever 13 published what you have testified under oath 14 today? 15 MR. NIGH: Form objection. And at 05:31 PM 16 this point, there's -- I start to think 17 that you're getting more and more into 18 this badgering statement. You're 19 pursing your lips, you're pointing, your 20 hitting the table. 05:31 PM 21 MR. FOWLER: I'm flabbergasted, 22 Counsel, because I'm trying to 23 understand this witness's testimony. 24 MR. NIGH: I know, but we have 25 still have to keep within the boundaries 05:31 PM</p>
<p style="text-align: right;">Page 319</p> <p>1 A. I just said that -- I'm 2 clarifying. So the FDA -- what I'm 3 clarifying, so IARC, EMA, EPA, Health Canada 4 have all said that this is a genotoxic 5 carcinogen that has no threshold and 05:29 PM 6 therefore it is not safe and exposure should 7 be minimized. 8 BY MR. FOWLER: 9 Q. First of all, my question was FDA. 10 I'll tackle the others in a second. 05:29 PM 11 To be crystal clear, FDA has never 12 published that NDMA has no threshold, sir. 13 Please answer that one question. 14 MR. NIGH: Form objection. 15 A. I corrected my statement. 05:30 PM 16 BY MR. FOWLER: 17 Q. So I am correct -- 18 MR. NIGH: Form objection. 19 A. Right. Like I said -- 20 Q. Okay. 05:30 PM 21 A. -- I rely on peer-reviewed papers 22 in the end. And I cited Peto et al., 23 Terracini 1967, and other papers in my report 24 that show, in animal experiments, that there 25 is no threshold, based on a linear 05:30 PM</p>	<p style="text-align: right;">Page 321</p> <p>1 of -- 2 MR. FOWLER: Absolutely. 3 THE WITNESS: Sorry I need to 4 clarify. 5 BY MR. FOWLER: 05:31 PM 6 Q. Thank you. 7 A. So there are peer-reviewed papers, 8 like I mentioned, Peto, et al., Terracini and 9 others that I cite in my report. And then 10 these agencies, and you're correct, they 05:31 PM 11 don't have peer-reviewed publications. They 12 come out with their statement, after they 13 met, it's a -- their opinion. So it's a 14 20/20 EMA assessment report. It's not a 15 peer-reviewed paper. 05:31 PM 16 And same thing, US Health Canada, 17 the EPA will come out with their 18 recommendations and so I -- to clarify, these 19 are not peer-reviewed, but these are based on 20 other -- leading scientists and their 05:32 PM 21 peer-reviewed papers, and then these 22 regulatory agencies will then determine risk 23 assessment. 24 And based on IARC's and other 25 peer-reviewed papers, that's how they come up 05:32 PM</p>


<p style="text-align: right;">Page 322</p> <p>1 with their risk assessment.</p> <p>2 Q. And when you say that EMA and</p> <p>3 Health Canada and others publish</p> <p>4 nonpeer-reviewed statements, Doctor, in none</p> <p>5 of those published statements do any of the 05:32 PM</p> <p>6 agencies you're talking about conclude that</p> <p>7 NDMA and NDEA have no threshold, in none of</p> <p>8 those published statements do those agencies</p> <p>9 say that, right?</p> <p>10 MR. NIGH: Form objection. 05:32 PM</p> <p>11 A. No, I disagree.</p> <p>12 BY MR. FOWLER:</p> <p>13 Q. Okay. Then I'll move on, Doctor.</p> <p>14 Returning to the Waddell article,</p> <p>15 this was 2003 and that was after Peto, right? 05:33 PM</p> <p>16 A. 2006, it looks like.</p> <p>17 Q. Thank you. 2006.</p> <p>18 And that was even further after</p> <p>19 Peto? No, to be honest, Doctor, this is</p> <p>20 2003. 05:33 PM</p> <p>21 A. Am I looking at the wrong one?</p> <p>22 Q. Are we looking at the same</p> <p>23 exhibit? The thresholds for carcinogenicity,</p> <p>24 sir.</p> <p>25 A. Oh, no, I'm looking at Waddell. 05:33 PM</p>	<p style="text-align: right;">Page 324</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. Now, sir, this is also by William</p> <p>3 Waddell. It's 2003.</p> <p>4 This was published after Peto,</p> <p>5 correct, sir? 05:34 PM</p> <p>6 A. Correct.</p> <p>7 Q. And it's entitled "Thresholds and</p> <p>8 Chemical Carcinogenesis: What Are Animal</p> <p>9 Experiments Telling Us?" And there's a</p> <p>10 question mark in the title. 05:34 PM</p> <p>11 Doctor, looking to -- first of</p> <p>12 all, are you familiar with this publication,</p> <p>13 Toxicologic Pathology, sir? Is the name of</p> <p>14 the journal, sir.</p> <p>15 A. Yes, I know, yes, the journal. 05:35 PM</p> <p>16 Q. And this is peer reviewed?</p> <p>17 A. Well, this looks like a review.</p> <p>18 Q. I'm just asking about the journal,</p> <p>19 sir.</p> <p>20 A. Yeah, the journal -- yeah, 05:35 PM</p> <p>21 primary, original papers are reviewed, but</p> <p>22 this looks like -- are peer reviewed. This</p> <p>23 is a review, so this is more of an opinion</p> <p>24 piece.</p> <p>25 Q. Doctor, to get published in 05:35 PM</p>
<p style="text-align: right;">Page 323</p> <p>1 Q. This is Waddell, sir. Waddell</p> <p>2 perspective, is that at the top?</p> <p>3 THE REPORTER: Hold on, gentlemen.</p> <p>4 We really need to get one at a time</p> <p>5 there. Sorry. 05:33 PM</p> <p>6 MR. NIGH: Yes, we do need to slow</p> <p>7 it down. The pace is getting too fast</p> <p>8 here.</p> <p>9 MR. FOWLER: This is the next</p> <p>10 exhibit. You know what, I was looking 05:33 PM</p> <p>11 at the wrong Waddell. You can rest</p> <p>12 that, sir.</p> <p>13 BY MR. FOWLER:</p> <p>14 Q. And we agree that that was</p> <p>15 published after Peto? 05:33 PM</p> <p>16 A. Yeah.</p> <p>17 Q. And Peto is one of the articles</p> <p>18 that you're hanging your hat on for your</p> <p>19 opinion that there's no threshold?</p> <p>20 A. Correct. 05:33 PM</p> <p>21 Q. Okay. Perfect.</p> <p>22 MR. FOWLER: 16.</p> <p>23 (Exhibit 16, Thresholds in Chemical</p> <p>24 Carcinogenesis: What Are Animal Experiments</p> <p>25 Telling Us, marked for identification.) 05:34 PM</p>	<p style="text-align: right;">Page 325</p> <p>1 Toxicologic Pathology, this, whatever you</p> <p>2 want to call it, perspective opinion piece</p> <p>3 would be peer reviewed, correct?</p> <p>4 MR. NIGH: Form objection.</p> <p>5 A. Yes, but a review process for a 05:35 PM</p> <p>6 review is very different from the review</p> <p>7 process for an original article.</p> <p>8 BY MR. FOWLER:</p> <p>9 Q. Okay. Fair enough.</p> <p>10 Directing your attention to the 05:35 PM</p> <p>11 first column, sir, towards the bottom, and I</p> <p>12 quote, "Now that threshold doses have been</p> <p>13 shown unequivocally to exist in the EDO1,"</p> <p>14 citing the Peto et al."</p> <p>15 Do you see where I read there, 05:36 PM</p> <p>16 sir?</p> <p>17 A. Yeah.</p> <p>18 Q. And if you look at reference 4,</p> <p>19 that is Peto 1991, the article that you rely</p> <p>20 upon for your contention that there is no 05:36 PM</p> <p>21 threshold, correct?</p> <p>22 MR. NIGH: Form objection.</p> <p>23 A. Correct.</p> <p>24 BY MR. FOWLER:</p> <p>25 Q. And this statement, 05:36 PM</p>

<p style="text-align: right;">Page 326</p> <p>1 "unequivocally," that's the term the authors 2 use, unequivocally there have been shown to 3 be thresholds using the very same study that 4 you rely on in your nonpeer-reviewed report, 5 correct? 05:36 PM 6 MR. NIGH: Form objection. 7 A. Well, I rely on peer-reviewed 8 papers in my report. 9 BY MR. FOWLER: 10 Q. Yes, sir. And you rely on Peto, 05:36 PM 11 and these authors, in a peer-reviewed 12 journal, have stated that same Peto data that 13 you contend shows no threshold, says 14 "threshold doses have been shown 15 unequivocally to exist"? 05:36 PM 16 MR. NIGH: Form objection. 17 A. So in science -- anyone can have 18 an opinion, first of all. So anybody -- you 19 can have a review process. There are 20 multiple publications that show nongenotoxic 05:37 PM 21 carcinogens have a threshold, and genotoxic 22 carcinogens, when you do a linear response, 23 do not have a threshold. 24 Not only did I cite Peto et al., 25 which other people have also cited as having 05:37 PM</p>	<p style="text-align: right;">Page 328</p> <p>1 Q. So we have -- 2 MR. NIGH: Hold on. Hold on. 3 Form objection to "scorecard." 4 MR. FOWLER: Just making sure 5 Mr. Nigh is paying attention here. 05:38 PM 6 BY MR. FOWLER: 7 Q. So we're up to three articles. In 8 the articles they state there is a threshold. 9 One was specific for NDEA. The other is for 10 NDMA, that was Dr. Waddell. That's where we 05:39 PM 11 are at the moment, sir. 12 A. Okay. 13 THE REPORTER: Counsel, I'm going 14 to need to take a break. 15 THE VIDEOGRAPHER: The time is 05:39 PM 16 5:38. We're off the record. 17 (Off-the-video-record discussion.) 18 THE REPORTER: You're ordering the 19 the original, right? 20 MR. HARKINS: Yeah. Original. 05:47 PM 21 I'm sure we have a standing for all 22 this. But we want everyone's transcript 23 you can think of. 24 THE REPORTER: Mr. Nigh, you're 25 getting the copy? 05:47 PM</p>
<p style="text-align: right;">Page 327</p> <p>1 no threshold, and I cited other papers, like 2 I mentioned, Terracini 1967, where they 3 used -- every dose that caused cancer in 4 those animals -- every dose caused cancer in 5 those animals, as low as two part per 05:37 PM 6 million, five part per million and higher. 7 So because we have hundreds of papers on NDMA 8 and NDEA causing cancer, the overwhelming 9 evidence in the literature is that this is a 10 potent carcinogen with no threshold. 05:38 PM 11 Q. Doctor, my question and the 12 questions for the next 30 minutes are going 13 to be a threshold level, okay. All right. 14 That's where we are right at this moment. 15 We're talking threshold. Okay. Just keeping 05:38 PM 16 us all on the same page. 17 And I've now shown you one, two 18 -- three articles from three different 19 journals that say there is a threshold, and 20 two of them rely upon the same article that 05:38 PM 21 you rely upon claiming there's not. Right? 22 That's where we are, that's the scorecard? 23 A. Well, I would say that one is a 24 review from the original paper that -- 25 Waddell that you mentioned. So that's -- 05:38 PM</p>	<p style="text-align: right;">Page 329</p> <p>1 MR. NIGH: Yes. 2 THE REPORTER: Do you know if 3 you're getting a rough? 4 MR. NIGH: Yes. 5 THE REPORTER: Ms. Bogdan? 05:47 PM 6 MR. NIGH: We only need to get one 7 on the Plaintiffs' side. 8 THE REPORTER: Who is ordering a 9 copy? 10 (Off-the-record discussion.) 05:48 PM 11 MR. HARKINS: For the court 12 reporter, if people want to communicate 13 their orders regarding the transcript, 14 while we're on this break, go ahead and 15 start doing that now. 05:48 PM 16 MR. BALL: We've already done 17 that. We emailed her. We emailed 18 Veritext. 19 THE REPORTER: Is that for 20 everybody that's on the Zoom? 05:49 PM 21 MR. BALL: No, it's for Duane 22 Morris. 23 THE REPORTER: Anybody else on the 24 Zoom getting a copy? 25 UNIDENTIFIED SPEAKER: If I order, 05:49 PM</p>

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1 I'll order at the end of day 2.
 2 MS. HEINZ: Jessica Heinz, I think
 3 we have a standing order with Veritext.
 4 THE REPORTER: Jessica, do you
 5 know if you get a rough? 05:49 PM
 6 MS. HEINZ: No, we don't get a
 7 rough usually.
 8 THE REPORTER: Can anybody on the
 9 Zoom tell me if they have the real-time?
 10 MR. BALL: Coleen Hill from Duane 05:49 PM
 11 Morris has the real-time.
 12 (Deposition suspended 5:50 p.m.)
 13
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1 COMMONWEALTH OF MASSACHUSETTS
 2 SUFFOLK, SS.
 3
 4 I, Sandra A. Deschaine, Registered
 5 Professional Reporter and Notary Public
 6 within and for the Commonwealth of
 7 Massachusetts at large, do hereby certify
 8 that the videotaped deposition of Dipak
 9 Panigrahy, M.D., in the matter of In Re:
 10 Valsartan, Losartan and Irbesartan Products
 11 Liability Litigation, at the offices of
 12 Greenberg Traurig, One International Place,
 13 Boston, Massachusetts, on September 9, 2021,
 14 taken and transcribed by me; that the witness
 15 provided satisfactory evidence of
 16 identification as prescribed by Executive
 17 Order 455 (03-13) issued by the Governor of
 18 the Commonwealth of Massachusetts; that the
 19 transcript produced by me is a true record of
 20 the proceedings to the best of my ability;
 21 that the witness is reading and signing; that
 22 I am neither counsel for, related to, nor
 23 employed by any of the parties to the action
 24 in which this deposition was taken, and
 25 further that I am not a relative or employee
 of any attorney or counsel employed by the
 parties thereto, nor financially or otherwise
 interested in the outcome of the action, on
 this 16th day of September 2021.
 18
 19 
 20 Sandra A. Deschaine
 21 Registered Professional Reporter
 22
 23
 24
 25 My Commission Expires:
 25 July 5, 2024

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1 SIGNATURE PAGE
 2 IN RE: VALSARTAN, LOSARTAN AND IRBESARTAN
 3 DIPAK PANIGRAHY, M.D. - SEPTEMBER 9, 2021
 4
 5 I, the undersigned, declare under penalty
 6 of perjury that I have read the foregoing
 7 transcript, and I have made any corrections,
 8 additions or deletions that I was desirous of
 9 making; that the foregoing is a true and
 10 correct transcript of my testimony contained
 11 therein.
 12
 13 Executed this _____ day of
 14 _____,
 15
 16 at _____, _____.
 17 (CITY) (STATE)
 18
 19 -----
 20 DIPAK PANIGRAHY, M.D.
 21
 22
 23
 24
 25

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1 ERRATA SHEET
 2 VERITEXT LEGAL SOLUTIONS
 3
 4 CASE NAME: In Re: Valsartan, Losartan, Et Al v.
 5 DATE OF DEPOSITION: 9/9/2021
 6 WITNESSES' NAME: Dipak Panigraphy, MD
 7
 8
 9
 10
 11
 12
 13
 14
 15
 16
 17
 18
 19
 20
 21
 22 Dipak Panigraphy, MD
 23 SUBSCRIBED AND SWORN TO BEFORE ME
 24 THIS ____ DAY OF _____, 20____.
 25
 25 (NOTARY PUBLIC) MY COMMISSION EXPIRES:

[& - 03:01]

Page 1

&	02:02 185:15,20 185:25	02:22 201:10,15 201:20,25	02:42 219:20,25 220:5,10
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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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1 UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3 Case No. 1:19-md-2875-RBK

4 _____)
IN RE: VALSARTAN, LOSARTAN AND)
5 IRBESARTAN PRODUCTS LIABILITY)
LITIGATION,)
6)
7)
THIS DOCUMENT RELATES TO ALL ACTIONS)
8)
9 -----)

10 DAY 2

11 CONFIDENTIAL

12 VIDEOTAPED DEPOSITION OF

13 DIPAK PANIGRAHY, M.D.

14 FRIDAY, SEPTEMBER 10, 2021

15 8:49 a.m. - 2:32 p.m.

16 GREENBERG TRAURIG LLP

17 ONE INTERNATIONAL PLACE, SUITE 2000

18 BOSTON, MASSACHUSETTS
19
20
21
22

23 Reported by: Sandra A. Deschaine, CSR, RPR,
24 CLR, CRA

25 Job No. 4769072

<p style="text-align: right;">Page 335</p> <p>1 SEPTEMBER 10, 2021</p> <p>2</p> <p>3 8:49 a.m.</p> <p>4</p> <p>5 Videotaped Deposition of Dipak</p> <p>6 Panigrahy, M.D., Day 2, held at Greenberg</p> <p>7 Taurig, LLP, One International Place, Boston,</p> <p>8 Massachusetts, pursuant to Notice, before</p> <p>9 Sandra A. Deschaine, a Shorthand Reporter,</p> <p>10 Registered Professional Reporter, Certified</p> <p>11 LiveNote Reporter, and Notary Public in and</p> <p>12 for the Commonwealth of Massachusetts.</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 337</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2 ON BEHALF OF THE PLAINTIFFS:</p> <p>3 MARTIN HARDING & MAZZOTTI LLP</p> <p>4 Rosemarie Bogdan, Esquire</p> <p>5 1 Wall Street</p> <p>6 Albany, New York 12205</p> <p>7 518.862.1200</p> <p>8 rosemarie.bogdan@1800law1010.com</p> <p>9</p> <p>10 ON BEHALF OF THE PLAINTIFFS:</p> <p>11 KANNER & WHITELEY, LLC</p> <p>12 Layne Hilton, Esquire (Via Zoom)</p> <p>13 701 Camp Street</p> <p>14 New Orleans, Louisiana 70130</p> <p>15 504.524.5777</p> <p>16</p> <p>17 ON BEHALF OF HJ HARKINS AND CIJEN:</p> <p>18 HINSHAW & CULBERTSON</p> <p>19 Kathleen Kelly, Esquire (Via Zoom)</p> <p>20 53 State Street, 27th Floor</p> <p>21 Boston, Massachusetts 02109</p> <p>22 617.231.7000</p> <p>23 kekelley@hinshawlaw.com</p> <p>24</p> <p>25 (Appearances continued.)</p>
<p style="text-align: right;">Page 336</p> <p>1 A P P E A R A N C E S:</p> <p>2 ON BEHALF OF TEVA PHARMACEUTICALS:</p> <p>3 GREENBERG TRAUIG LLP</p> <p>4 Stephen Fowler, Esquire</p> <p>5 2101 L Street, N.W., Suite 1000</p> <p>6 Washington, D.C. 20037</p> <p>7 202.530.8587</p> <p>8 fowlerst@gtlaw.com</p> <p>9 and</p> <p>10 Steven Harkins, Esquire</p> <p>11 Kenneth Dzikowski, Esquire (Via Zoom)</p> <p>12 333 Piedmont Road NE, Suite 2500</p> <p>13 Atlanta, Georgia 30350</p> <p>14 678.553.2312</p> <p>15 harkinss@gtlaw.com</p> <p>16</p> <p>17 ON BEHALF OF THE PLAINTIFFS AND THE WITNESS:</p> <p>18 LEVIN PAPANTONIO RAFFERTY</p> <p>19 Daniel Nigh, Esquire</p> <p>20 316 South Baylen Street</p> <p>21 Pensacola, Florida 32502</p> <p>22 850.435.7013</p> <p>23 dnigh@levinlaw.com</p> <p>24</p> <p>25 (Appearances continued.)</p>	<p style="text-align: right;">Page 338</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2 ON BEHALF OF AUROBINDO PHARMA LIMITED:</p> <p>3 CIPRIANI & WERNER, P.C.</p> <p>4 Jessica Heinz, Esquire (Via Zoom)</p> <p>5 450 Sentry Parkway, Suite 200</p> <p>6 Blue Bell, Pennsylvania 19422</p> <p>7 610.567.0700</p> <p>8 jheinz@c-wlaw.com</p> <p>9</p> <p>10 ON BEHALF OF HUMANA PHARMACY, INC.:</p> <p>11 FALKENBERG IVES LLP</p> <p>12 Megan Zmick, Esquire (Via Zoom)</p> <p>13 230 W. Monroe Street, Suite 2220</p> <p>14 Chicago Illinois 60606</p> <p>15 312.566.4808</p> <p>16 maz@falkenbergives.com</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 (Appearances continued.)</p>

<p style="text-align: right;">Page 339</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2 ON BEHALF OF MYLAN PHARMACEUTICALS:</p> <p>3 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI</p> <p>4 LLP:</p> <p>5 Clem Trischler, Esquire (Via Zoom)</p> <p>6 Frank Stoy, Esquire (Via Zoom)</p> <p>7 Jason Reefer, Esquire (Via Zoom)</p> <p>8 Bradley Matta, Esquire (Via Zoom)</p> <p>9 One Oxford Centre</p> <p>10 Pittsburgh, Pennsylvania 15219</p> <p>11 412.263.4246</p> <p>12 cct@pietragallos.com</p> <p>13 fhs@pietragallos.com</p> <p>14</p> <p>15 ON BEHALF OF THE DEFENDANTS ZHEJIANG HUAHAI</p> <p>16 PHARMACEUTICAL CO., LTD., PRINSTON</p> <p>17 PHARMACEUTICAL, INC., AND SOLCO HEALTHCARE</p> <p>18 LLC AND HUAHAI U.S., INC.:</p> <p>19 DUANE MORRIS LLP</p> <p>20 Frederick Ball, Esquire (Via Zoom)</p> <p>21 100 High Street, Suite 2400</p> <p>22 Boston, Massachusetts 02110-1724</p> <p>23 312.277.1945</p> <p>24 frball@duanemorris.com</p> <p>25 (Appearances continued.)</p>	<p style="text-align: right;">Page 341</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2</p> <p>3 ON BEHALF ALBERTSON'S LLC:</p> <p>4 BUCHANAN INGERSOLL & ROONEY PC</p> <p>5 Christopher Henry, Esquire (Via Zoom)</p> <p>6 227 West Trade Street, Suite 600</p> <p>7 Charlotte, North Carolina 28202</p> <p>8 704.444.3475</p> <p>9 christopher.henry@bipc.com</p> <p>10</p> <p>11 ON BEHALF OF HETERO DRUGS AND HETERO LABS:</p> <p>12 HILL WALLACK LLP</p> <p>13 Nakul Shah, Esquire (Via Zoom)</p> <p>14 21 Roszel Road</p> <p>15 P.O. Box 5226</p> <p>16 Princeton, New Jersey 08543-5226</p> <p>17 nshah@hillwallack.com</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 (Appearances continued.)</p>
<p style="text-align: right;">Page 340</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2</p> <p>3 ON BEHALF OF CVS AND RITE AID:</p> <p>4 BARNES & THORNBURG, LLP</p> <p>5 Kara Kapke, Esquire (Via Zoom)</p> <p>6 11 S. Meridian Street</p> <p>7 Indianapolis, Indiana 46204-3535</p> <p>8 317.231.6491</p> <p>9 kara.kapke@btlaw.com</p> <p>10</p> <p>11 ON BEHALF OF TEVE PHARMACEUTICALS:</p> <p>12 WALSH PIZZI O'REILLY FALANGA LLP</p> <p>13 Christine Gannon, Esquire (Via Zoom)</p> <p>14 Three Gateway Center</p> <p>15 100 Mulberry Street, 15th Floor</p> <p>16 Newark, New Jersey 07102</p> <p>17 973.757.1100</p> <p>18 cgannon@walsh.law</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 (Appearances continued.)</p>	<p style="text-align: right;">Page 342</p> <p>1 A P P E A R A N C E S (continued.)</p> <p>2 Also Present: Bob Giannini, videographer</p> <p>3 (Below via Zoom.)</p> <p>4 Ben Pelta Heller, concierge</p> <p>5 Coleen Hill, Duane Morris</p> <p>6 Dolores DeSalvo, Martin</p> <p>7 Hardinger & Mazzotti</p> <p>8 Ken Pzikowski</p> <p>9 Lauren Massey</p> <p>10 Liza Walsh</p> <p>11 Brett Vaughn</p> <p>12 Chicago37B</p> <p>13 16092139142</p> <p>14 14127134023</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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1
2 PROCEEDINGS
3 THE VIDEOGRAPHER: Good morning.
4 We are on the record. Today's date is
5 September 10th, 2021, and the time is 11:13 AM
6 8:49 a.m. This is Day 2 of Dipak
7 Panigrahy. The witness has been sworn
8 in. You may proceed.
9 CONTINUED EXAMINATION
10 BY MR. FOWLER: 08:49 AM
11 Q. Good morning, Doctor. After we
12 concluded yesterday, did you review anything
13 between last evening and this morning?
14 A. Yes. I had reviewed the papers
15 that you had asked me to -- my entire file of 08:50 AM
16 printed papers.
17 Q. Yes, sir.
18 A. You had asked me to give you the
19 printed papers.
20 Q. Oh, these are in addition to what 08:50 AM
21 you brought with you yesterday?
22 A. Yes, these are new.
23 Q. Okay.
24 A. These are new files.
25 Q. Thank you. 08:50 AM

1 Are these papers, papers that you
2 cite in your report?
3 A. Yes. Yes.
4 Q. Okay. And the underlining is
5 yours? 08:50 AM
6 A. It's me, yes.
7 MR. NIGH: And I'll represent that
8 we believe all of those papers are also
9 in the Dropbox, but I don't think that
10 they have some of the writing and 08:50 AM
11 underlining on it.
12 MR. FOWLER: Yes, sir.
13 BY MR. FOWLER:
14 Q. Doctor, yesterday, when you
15 referenced the 1970 Nature journal and a 08:51 AM
16 particular -- I don't want to call it an
17 article, but information contained in that
18 journal from 1970, were you referring to
19 this -- this part that says metabolism of
20 dimethyl -- of NDMA and human liver slices? 08:51 AM
21 Is that what you were speaking of yesterday?
22 A. Correct.
23 Q. And that's the extent of what you
24 were speaking about in the Nature 1970
25 journal? 08:52 AM

<p style="text-align: right;">Page 347</p> <p>1 A. Yes, this was the paper I was 2 referring to. 3 Q. Okay. And it states, in the 4 concluding paragraph, "Although the 5 significance alkylation of nucleic acid and 08:52 AM 6 carcinogenesis by nitrosamines is not known, 7 there's a correlation between the levels of 8 methylation and an organ and the distribution 9 of tumors in rats treated with NDMA." 10 Do you understand that to say that 08:52 AM 11 there was no understanding -- no definitive 12 understanding of NDMA and carcinogenesis at 13 the time that this was written? 14 MR. NIGH: Form objection. 15 A. So when they wrote that in the 08:52 AM 16 context of 1970, it was already known that -- 17 we knew from 1954 studies, the field knew in 18 1956, that Magee had shown in rats that NDMA 19 could cause cancer; that was in 1956. 20 And then in the 1960s, there were 08:53 AM 21 multiple publications, which I've cited in my 22 report, Terracini et al., 1964, Terracini et 23 al. 1967, that NDMA can cause cancer in 24 animals. 25 So as I said before, in science 08:53 AM</p>	<p style="text-align: right;">Page 349</p> <p>1 human tissue -- and the human liver tissue. 2 Q. And the high-profile paper is the 3 a total of two columns published in Nature, 4 correct? 5 MR. NIGH: Form objection. 08:55 AM 6 A. Yeah, so in science many of the -- 7 many of the pioneering studies, it's not the 8 length of the paper, it's the concept that 9 you bring out. 10 And then -- what's important in 08:55 AM 11 science is they publish that in 1970, but 12 then Autrup Harris and other colleagues 13 showed in a series of six or seven 14 publications, which I cited in my report, 15 then they confirmed this by taking human 08:55 AM 16 bronchus, which is lung, human esophagus, 17 human bladder, human colon, human pancreas, 18 and they took those cells from these human 19 tissues and they showed, in a similar 20 fashion, that the metabolism, using these 08:56 AM 21 human cells, when they expose it to NDMA, you 22 get a virtually identical mechanism of action 23 as in animals. 24 Q. And can we agree, what you're 25 describing is qualitative not quantitative 08:56 AM</p>
<p style="text-align: right;">Page 348</p> <p>1 when you write a paper, it's in the context 2 of what's known in the field at the time. So 3 people had known that NDMA could cause cancer 4 in these animals, and then what Monsanto and 5 Magee looked in this Nature publication, in 08:53 AM 6 1970, was to compare the metabolism of the 7 NDMA in animals to humans, and that's where 8 they took human liver slices and compared 9 liver to animals, such as rats, and then they 10 exposed those cells from human tissue to 08:54 AM 11 animal tissue to NDMA, and they looked at the 12 metabolism. 13 And one of the readouts of the 14 metabolism is a formation of these adducts, 15 and one of the readouts for that is carbon 08:54 AM 16 dioxide production, aldehyde production and 17 they quantified that. And their conclusion 18 was the metabolism in the animals was 19 virtually identical to the mechanism of 20 action of metabolism in humans. 08:54 AM 21 So in the context of knowing that 22 NDMA causes cancer in animals, the next step 23 would have been to look at mechanisms that 24 are relevant to humans. And the reason why 25 this was a high-profile paper, is they used 08:54 AM</p>	<p style="text-align: right;">Page 350</p> <p>1 information, correct? 2 MR. NIGH: Form objection. 3 A. The readout -- 4 Q. Correct? 5 MR. NIGH: No. No. No. He's 08:56 AM 6 answering the question. 7 A. Qualitative and quantitative -- 8 quantitative can be measured in a readout. 9 So they use percent carbon dioxide that's -- 10 THE REPORTER: I'm sorry, "they 08:56 AM 11 use percent"? 12 THE WITNESS: -- percent carbon 13 dioxide that's excel, that's a 14 quantitative measure. 15 BY MR. FOWLER: 08:56 AM 16 Q. Can I ask it this way? 17 When you're describing mechanisms, 18 can we agree you're describing the 19 qualitative response when you say there was 20 similar -- strike that question. I'll move 08:56 AM 21 on. 22 Doctor, also contained in this, 23 and I'm going to mark this subsequent set 24 as Exhibit -- are we up to 16? 25 MR. NIGH: 17. 08:57 AM</p>

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<p style="text-align: right;">Page 351</p> <p>1 MR. FOWLER: Okay. I'm off to a 2 good start. 3 BY MR. FOWLER: 4 Q. Exhibit 17 will be this 5 compilation. And we'll mark it here in a 08:57 AM 6 minute. 7 As I'm going through it, Doctor, 8 you also have in here a 1974 article by 9 Cardesa, "Comparative studies of neoplastic 10 response to a signal dose of nitroso 08:57 AM 11 compounds." 12 This is something you rely upon 13 for your single dose theory, correct, sir? 14 MR. NIGH: Form objection. 15 A. Well, single dose -- I relied on 08:57 AM 16 this paper in my 580 reference -- 17 Q. Yes, sir. 18 A. -- but it's not a theory. What's 19 said in the paper is that a single dose of 20 NDMA can cause cancer in animals. 08:57 AM 21 Q. Yes, sir. 22 A. But what's important is that it's 23 not in one species. As we were talking about 24 yesterday, what's important, we have to know 25 that this assay, the chemical carcinogenesis 08:57 AM</p>	<p style="text-align: right;">Page 353</p> <p>1 rate would be how much in a 60-kilogram 2 human, sir? 3 MR. NIGH: Form objection. 4 MR. FOWLER: What's wrong with 5 that question? 08:59 AM 6 MR. NIGH: You really want the 7 reason? 8 MR. FOWLER: I do. I want to know 9 what's your objection to that question, 10 asking him what that equates to in 08:59 AM 11 humans, please; what's your objection? 12 MR. NIGH: I don't have to give 13 the reason for my objection. 14 MR. FOWLER: I think the judge 15 actually requested that you give a 08:59 AM 16 reason not just form. 17 MR. NIGH: Actually, he didn't. 18 MR. FOWLER: I want to cure it. 19 Counsel, you've made an objection. I'd 20 like to know the basis so I can cure it. 08:59 AM 21 What's wrong with that question? 22 MR. NIGH: There's never been a 23 statement that we have to give the 24 reason for my form objection. 25 MR. FOWLER: I'm asking you right 08:59 AM</p>
<p style="text-align: right;">Page 352</p> <p>1 assay, where you give a chemical to animals 2 for causation of cancer, is the single most 3 important assay when you're screening, to 4 start the question, does a chemical cause 5 cancer? And you start with the chemical 08:58 AM 6 biogenesis assay. 7 These chemicals, NDMA and NDEA, 8 are so potent that a single dose can cause 9 cancer in multiple species. And that's where 10 I said it was 20 substrains of mice, 60 08:58 AM 11 substrain of -- you know, 20 to 60 substrains 12 of mouse and rats, fish, you know, hamsters. 13 So the point -- and the fact that a single 14 dose of NDMA or NDA can cause cancer, that's 15 not a theory. 08:58 AM 16 Q. I'm presenting you with this 17 study, and we're going -- this is part of 18 your collection. 19 Tell me, Doctor, what is the 20 lowest single dose that was given to the 08:59 AM 21 animals in this single dose study? It's on 22 that chart on the second page, correct? 23 A. Yeah. So for NDMA, it looks like 24 they give 8. -- 0.5 mgs per kg body weight. 25 Q. Yes, sir. And .5 mgs per kg body 08:59 AM</p>	<p style="text-align: right;">Page 354</p> <p>1 now what the basis for that objection 2 is. I feel -- what's the basis for that 3 objection? 4 MR. NIGH: And I've stated 5 previously that I don't have to give a 09:00 AM 6 reason for my form objection. 7 MR. FOWLER: I feel like that is 8 an improper objection to that 9 question. 10 MR. NIGH: Objection. 09:00 AM 11 MR. FOWLER: What is your basis? 12 You don't want to tell me? 13 MR. NIGH: You're entitled to your 14 opinion, and I don't have to give a 15 reason for the basis of my form 09:00 AM 16 objection. 17 MR. FOWLER: I think littering 18 this record with improper objections is 19 inappropriate, and I've asked you what 20 the basis is for that -- you want to 09:00 AM 21 withdraw the objection? 22 MR. NIGH: No, I do not. I 23 actually believe that it's an 24 appropriate objection. 25 MR. FOWLER: Can I have the 09:00 AM</p>

6 (Pages 351 - 354)

<p style="text-align: right;">Page 355</p> <p>1 question read back, please?</p> <p>2 THE REPORTER: Hold on.</p> <p>3 "And .5 mgs per kg body rate would</p> <p>4 be how much in a 60-kilogram human,</p> <p>5 sir?" 08:59 AM</p> <p>6 MR. FOWLER: That wasn't the</p> <p>7 questions. Let me ask it again.</p> <p>8 THE REPORTER: That is the</p> <p>9 question.</p> <p>10 MR. NIGH: That was the question. 08:59 AM</p> <p>11 MR. FOWLER: I said 60 --</p> <p>12 THE REPORTER: Hold on. I need to</p> <p>13 have my hands on -- so I just read that.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. Sir, .5 mgs per kg was the lowest 08:59 AM</p> <p>16 dose given in that single dose study,</p> <p>17 correct?</p> <p>18 A. Right.</p> <p>19 Q. And in a 60-kilogram human, what</p> <p>20 would that amount equate to? 09:01 AM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A. As I said yesterday, it's highly</p> <p>23 inappropriate for this mechanism of action to</p> <p>24 convert from body surface area and body</p> <p>25 weight in an animal to a human, because NDMA 09:01 AM</p>	<p style="text-align: right;">Page 357</p> <p>1 detected in any valsartan tablet; isn't that</p> <p>2 correct?</p> <p>3 A. As I mentioned yesterday, this is</p> <p>4 a genotoxic chemical, so there is no safe</p> <p>5 dose; there's no threshold. We know from 09:03 AM</p> <p>6 multiple years of experience with genotoxic</p> <p>7 carcinogens there's no safe dose, because</p> <p>8 even one molecule can induce DNA damage.</p> <p>9 Q. Yes, sir. If there's no safe</p> <p>10 dose, that means you completely disagree with 09:03 AM</p> <p>11 the FDA's 96 nanogram acceptable intake?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. No. So the FDA has given an</p> <p>14 acceptable intake that they -- that they</p> <p>15 calculated, and said that this is an amount 09:03 AM</p> <p>16 that shouldn't be exceeded. So for genotoxic</p> <p>17 carcinogens, what -- but, however, FDA, EMA,</p> <p>18 and as I said yesterday, they have said that</p> <p>19 you should minimize intake of these</p> <p>20 carcinogens. 09:04 AM</p> <p>21 Q. Doctor, how can you reconcile --</p> <p>22 how can you reconcile your single molecule or</p> <p>23 single dose therapy with FDA's 96 nanogram</p> <p>24 acceptable intake? How do you reconcile</p> <p>25 that? 09:04 AM</p>
<p style="text-align: right;">Page 356</p> <p>1 and NDEA, the mechanism of action, as we just</p> <p>2 talked about, is a generation of these very</p> <p>3 potent electrophilic alkylating adducts, and</p> <p>4 this mechanism of action is virtually</p> <p>5 identical in rodents and animals. 09:02 AM</p> <p>6 So that's why WHO, in 2002, and I</p> <p>7 quote, said "It is highly inappropriate to</p> <p>8 use a conversion between rodent, body weight,</p> <p>9 and surface area to humans."</p> <p>10 MR. NIGH: And I'm happy to give 09:02 AM</p> <p>11 the reason for my form objection, if</p> <p>12 you'd like, now.</p> <p>13 BY MR. FOWLER:</p> <p>14 Q. Doctor, .5 mgs per kg would be 30</p> <p>15 mgs -- 09:02 AM</p> <p>16 THE REPORTER: I just had a glitch</p> <p>17 there.</p> <p>18 "Doctor, .5 mgs per"?</p> <p>19 Q. .5 mgs per kg would be 30</p> <p>20 milligrams in a 60-kilogram human, correct? 09:02 AM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A. Yes, correct.</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. And that is thousands of time</p> <p>25 greater than the highest level that was 09:02 AM</p>	<p style="text-align: right;">Page 358</p> <p>1 A. So what the field has done is --</p> <p>2 has said that, and I'm quoting from EMA and</p> <p>3 other documents, that there is no safe level.</p> <p>4 However, because these are nitrosamines --</p> <p>5 that NDMA can be in the diet and that people 09:04 AM</p> <p>6 every day are subjected to a certain amount,</p> <p>7 the FDA came up, based on the dose on the</p> <p>8 linear extrapolation of Peto, came up --</p> <p>9 using the TD 50, came up with an acceptable</p> <p>10 index of NDMA, and it was 96 nanograms per 09:05 AM</p> <p>11 day, is what it comes out to.</p> <p>12 Q. And how do you reconcile FDA</p> <p>13 saying that amount is safe with your one</p> <p>14 molecule theory?</p> <p>15 MR. NIGH: Form objection. 09:05 AM</p> <p>16 A. So, like I said, it's not my</p> <p>17 theory. These are -- people have said</p> <p>18 genotoxic carcinogens and there's 50 years of</p> <p>19 scientific literature that shows that</p> <p>20 genotoxic carcinogens are very dangerous. 09:05 AM</p> <p>21 As I said yesterday, NDMA is not</p> <p>22 only genotoxic, mutagenic, clastogenic, that</p> <p>23 means it induces the cytochrome changes, it</p> <p>24 induces genomic instability, it alters DNA</p> <p>25 repair, it affects -- it increases oxidative 09:05 AM</p>

<p style="text-align: right;">Page 359</p> <p>1 stress, stimulates chronic inflammation, 2 suppresses -- it induces immunosuppression, 3 which suppresses the immune system, which is 4 in everybody's body to help protect from 5 cancers. NDMA stimulates proliferation; it 09:06 AM 6 stimulates angiogenesis, the growth of new 7 blood vessels, it can induce cell death, 8 which can stimulate tumor growth. 9 So all of these key 10 characteristics, which IARC has mentioned in 09:06 AM 11 the last eight years, are critical to the 12 mechanism of action of NDMA and NDEA and 13 causing cancer. 14 BY MR. FOWLER: 15 Q. Doctor, do you agree that your 09:06 AM 16 opinion in this case is inconsistent with the 17 FDA's 96 nanogram acceptable intake? 18 MR. NIGH: Form objection. 19 A. No. I was asked does the 20 exogenous -- does the amount of NDMA that's 09:06 AM 21 in these valsartan pills cause human cancer. 22 And I relied on not only -- as I mentioned 23 yesterday, not only do I rely on the key 24 animal experiments about causation and not 25 only the mechanistic studies, but the 09:07 AM</p>	<p style="text-align: right;">Page 361</p> <p>1 associated with an increased risk of at least 2 10 different cancers. 3 So the amount of NDMA in the 4 valsartan tablet -- in the contaminated 5 valsartan tablet is higher than these amounts 09:08 AM 6 that are in the Hidajat studies that are -- 7 over time and that are in the dietary 8 studies. 9 And as I mention in the report -- 10 I'll just read from the report here. 09:09 AM 11 "By way of illustration, a patient 12 taking 320 milligram per day of ZHP 13 valsartan (average contamination level 14 for product D5191 of 65.1 ppm) would 15 ingest 20,000 nanograms of NDMA per day. 09:09 AM 16 This patient would reach the cumulative 17 NDMA exposure for the bound of Quartile 18 II in 300 days (approximately 10 19 months), and this doesn't take into 20 account the threshold exposure to NDMA 09:09 AM 21 that a valsartan patient has because of 22 diet, which is estimated in the United 23 States range from .03 to .06 microgram 24 per day, depending on age, or even 0" -- 25 THE REPORTER: Or even 0? 09:10 AM</p>
<p style="text-align: right;">Page 360</p> <p>1 epidemiology studies have shown, and I've 2 cited, that the amounts of NDMA in these 3 dietary studies and the occupational studies, 4 such as Hidajat, the amount of NDMA that's in 5 those studies exceeds the amount that the FDA 09:07 AM 6 has allowed, 96 nanograms per day. And it 7 exceeds -- this increased amount is 8 associated with an increased risk of cancer. 9 So what's very important is the 10 exposure of these people to NDMA, increases 09:07 AM 11 your risk of cancer, and that increased risk 12 can be 10, 100, 200 times higher than what 13 the FDA has permitted. So the amount of NDMA 14 or NDEA in these tablets is on a fold of 20 15 to 200 times higher than what the FDA has 09:08 AM 16 allowed in their acceptable 96 nanogram per 17 day. 18 But what's even also important is 19 that the amount of NDMA that's in the diet of 20 these human epidemiology studies and in the 09:08 AM 21 occupational study of Hidajat, which 22 carefully took different quartiles, which in 23 Quartiles II, III and IV, that increasing 24 NDMA exposure, over a lifetime cumulative 25 exposure compared to baseline, that was 09:08 AM</p>	<p style="text-align: right;">Page 362</p> <p>1 THE WITNESS: "0.03 to 0.06 2 microgram per day, depending on age, or 3 0.08 microgram per day when beer is 4 included. 5 And as I go through -- in this 09:10 AM 6 section of the report, I used the 7 Bradford Hill criteria very carefully to 8 go through human epidemiology studies, 9 including Hidajat, the occupational -- 10 where they carefully quantified the 09:10 AM 11 amount of NDMA exposure, and then I went 12 through the dietary studies, which also 13 quantified the NDMA exposure. And these 14 studies in peer-reviewed journals 15 show -- many of these studies show a 09:10 AM 16 significant increased risk of cancer. 17 So by relying on this human 18 epidemiology data in conjunction -- 19 because as I said in science, we use all 20 levels of evidence -- so in conjunction 09:11 AM 21 with a chemical that can cause cancer in 22 animals very potently; and, in fact, as 23 I mentioned yesterday, routinely, 24 laboratories throughout the world use 25 NDMA and NDEA to initiate cancer, at 09:11 AM</p>

<p style="text-align: right;">Page 363</p> <p>1 least six different types of cancer.</p> <p>2 And in addition to that, the</p> <p>3 mechanism of action, which, as I said</p> <p>4 yesterday, that IARC has put an extreme</p> <p>5 emphasis, especially on chemicals that 09:11 AM</p> <p>6 cannot be tested routinely in humans,</p> <p>7 such as NDMA and NDA. We can't do</p> <p>8 randomized controlled trials. It would</p> <p>9 be unethical to give somebody -- to do a</p> <p>10 study -- an epidemiological study with 09:11 AM</p> <p>11 pure NDMA and NDA.</p> <p>12 They have said, since 2012 and</p> <p>13 published in 2016, and since 2019, every</p> <p>14 IARC monograph is now using the key</p> <p>15 characteristics, and that the key 09:12 AM</p> <p>16 characteristics are very important in</p> <p>17 the mechanism of action of how NDMA and</p> <p>18 NDEA cause cancer. And the 10 key</p> <p>19 characteristics, which I mentioned, NDMA</p> <p>20 and NDEA exhibit 9 of the 10 key 09:12 AM</p> <p>21 characteristics.</p> <p>22 So, in conclusion, I would say the</p> <p>23 combination of the human epi data, which</p> <p>24 carefully quantifies the amount of NDMA</p> <p>25 exposure to your increased risk of 09:12 AM</p>	<p style="text-align: right;">Page 365</p> <p>1 /</p> <p>2 BY MR. FOWLER:</p> <p>3 Q. Are you finished?</p> <p>4 A. Yeah.</p> <p>5 Q. Doctor, under your one molecule 09:13 AM</p> <p>6 theory, would you be able to tell a molecule</p> <p>7 from valsartan versus a molecule from a</p> <p>8 dietary intake?</p> <p>9 MR. NIGH: Form objection.</p> <p>10 A. I'm not sure I understand the 09:14 AM</p> <p>11 question. The question here, in this case,</p> <p>12 is NDMA -- not a question.</p> <p>13 Valsartan without NDMA -- are you</p> <p>14 asking one molecule --</p> <p>15 Q. Let me try again, Doctor. 09:14 AM</p> <p>16 You've expressed an opinion</p> <p>17 multiple times that you think one molecule</p> <p>18 would be a sufficient -- that one molecule</p> <p>19 can cause cancer. You've said that, correct?</p> <p>20 A. Yes. 09:14 AM</p> <p>21 Q. Okay. And, Doctor, if there is</p> <p>22 dietary intake of NDMA, you would not be able</p> <p>23 to opine whether a cancer arose from one</p> <p>24 molecule of dietary intake versus one</p> <p>25 molecule of NDMA from a valsartan tablet, 09:15 AM</p>
<p style="text-align: right;">Page 364</p> <p>1 cancers in humans, that combined with</p> <p>2 the animal data that this is a potent</p> <p>3 carcinogen that use to initiate cancer,</p> <p>4 combined with that the mechanism of</p> <p>5 action of NDMA in animals and humans is 09:12 AM</p> <p>6 virtually identical, is why the six</p> <p>7 agencies, and I agree with them, that</p> <p>8 EPA and IARC have classified NDMA and</p> <p>9 NDEA as probable human carcinogens.</p> <p>10 NTP and DHS, Department -- 09:13 AM</p> <p>11 THE REPORTER: NTP and?</p> <p>12 THE WITNESS: NTP, the National</p> <p>13 Toxicology Program, the U.S. National</p> <p>14 Toxicology Program, has said this is</p> <p>15 reasonably -- NDMA is reasonably 09:13 AM</p> <p>16 anticipated to be a human carcinogen,</p> <p>17 and the European Medical Association has</p> <p>18 agreed that this is a probable human</p> <p>19 carcinogen.</p> <p>20 And, in fact, the EMA, in their 09:13 AM</p> <p>21 assessment report from 2020, says that</p> <p>22 this is a genotoxic carcinogen and</p> <p>23 exposure should be avoided and limited.</p> <p>24 And then Health Canada also agreed with</p> <p>25 this assessment. 09:13 AM</p>	<p style="text-align: right;">Page 366</p> <p>1 could you?</p> <p>2 MR. NIGH: Form objection.</p> <p>3 A. The question here is the NDMA, in</p> <p>4 the valsartan tablet, is it causing cancer in</p> <p>5 humans. And here -- one molecule can cause 09:15 AM</p> <p>6 cancer. But as I just mentioned, it is</p> <p>7 highly -- it's more likely than not, through</p> <p>8 all these key characteristics, that the</p> <p>9 amount that's in these contaminated</p> <p>10 valsartan, based on the four lines of 09:15 AM</p> <p>11 evidence that I just mentioned, the human</p> <p>12 epi, the mechanism of action in animals and</p> <p>13 humans, and the causation in animals, that</p> <p>14 this is a human carcinogen and the human</p> <p>15 epidemiology data supports that the amount of 09:15 AM</p> <p>16 NDMA that's in these valsartan tablets is</p> <p>17 higher; and as I said in the report, 20- to</p> <p>18 200-fold higher than the permitted level that</p> <p>19 FDA has allowed.</p> <p>20 And the human epi studies that I 09:16 AM</p> <p>21 cited here, including Hidajat, inhalation,</p> <p>22 occupational study and the diet study, show</p> <p>23 that the amount of NDMA in these valsartan</p> <p>24 tablets could be reached by a patient, a</p> <p>25 person taking valsartan within 180 days, 09:16 AM</p>

<p style="text-align: right;">Page 367</p> <p>1 within six months. And the epi studies show 2 that that amount of NDMA is associated with a 3 significant increased risk of 10 different 4 cancers. 5 Q. How much time did you spend with 09:16 AM 6 counsel yesterday after we adjourned? 7 A. Probably about 20 minutes. I 8 mainly watched the Tampa Bay game and was on 9 my own. 10 MR. FOWLER: Let's mark the 17 on 09:17 AM 11 here before I forget, please. 12 (Exhibit 17, Records from Dipak Panigrahy, 13 marked for identification.) 14 MR. FOWLER: You can hand it to 15 him. I'm done with it for the time 09:17 AM 16 being. 17 BY MR. FOWLER: 18 Q. Doctor, do you understand that -- 19 let me start that again. 20 Do you know whether the FDA 96 09:17 AM 21 nanograms using the TD 50 linear back 22 extrapolation considers DNA repair? 23 MR. NIGH: Form objection. 24 A. So the documents I've read from 25 the FDA website, that anyone can download 09:18 AM</p>	<p style="text-align: right;">Page 369</p> <p>1 cancer causation and part of that process 2 does include DNA repair. 3 BY MR. FOWLER: 4 Q. So it's your testimony that the 5 TD 50 method accounts for DNA repair, sir? 09:20 AM 6 MR. NIGH: Form objection. 7 A. The FDA uses the TD 50 to 8 extrapolate an acceptable index of the amount 9 of NDMA that is allowed in -- exposed in 10 people. So I'm not understanding -- I don't 09:20 AM 11 think I understand the question then. 12 BY MR. FOWLER: 13 Q. Do you know whether or not the 14 TD 50 calculation, which I note from 15 yesterday you've never done, but does the 09:20 AM 16 TD 50 calculation account for DNA repair or 17 not, sir? 18 MR. NIGH: Objection. Hold on. 19 Form objection, and I object to the 20 colloquy in that question. 09:20 AM 21 A. I followed the TD 50 calculations 22 from the documents from scientific agencies 23 that have reported the TD 50. And the 24 important part of the TD 50 that the FDA 25 uses, is they base it on a 1991 Peto paper 09:21 AM</p>
<p style="text-align: right;">Page 368</p> <p>1 from the website, I don't believe -- I can't 2 recall if they specifically mentioned DNA 3 repair. But what I do remember they said, 4 that intake of NDMA should be avoided. 5 However, they come up with this acceptable 09:18 AM 6 index of 96 nanogram per day. But they do 7 say on the website, in documents that you can 8 just open up, that exposure should be 9 avoided. 10 Q. Doctor, does the TD 50 back 09:18 AM 11 extrapolation consider DNA repair? 12 A. So DNA repair, as I said, is one 13 of the 10 key characteristics. So cancer 14 causation and the mechanism of cancer does 15 consider DNA repair as part of key 09:19 AM 16 characteristic number 3. DNA repair is very 17 important in genomic instability. That's the 18 key characteristic number three; and as I 19 said, NDMA can affect nine of the ten, 20 including DNA repair. 09:19 AM 21 Q. Does the TD 50 linear back 22 extrapolation method consider DNA repair, 23 Doctor, that's my question? 24 MR. NIGH: Form objection. 25 A. So, as I just said, it considers 09:19 AM</p>	<p style="text-align: right;">Page 370</p> <p>1 that has linear curve and they extrapolate 2 from that the TD 50. And from there they can 3 calculate an acceptable index where they say 4 it's permitted that people are allowed 96 5 nanogram per day of NDMA. 09:21 AM 6 However, in this case, as I just 7 mentioned, the contaminated levels in the 8 valsartan tablets are 20- to 200-fold higher 9 than the amount that the FDA allows, based on 10 the acceptable index, which uses the TD 50. 09:21 AM 11 So whether DNA repair is involved 12 in the TD 50, really the question is, does 13 the levels of NDMA in these valsartan 14 tablets, is it higher than the FDA's 15 acceptable index? 09:22 AM 16 Q. And you think that that's the 17 question? You think that's the 18 determinative, that the levels in the 19 valsartan tablet exceed the FDA 96 nanograms? 20 MR. NIGH: Form objection. 09:22 AM 21 A. So as I mentioned -- so the 22 important part is that the human epi studies, 23 in conjunction with the animals studies and 24 the mechanistic studies, show an increased 25 risk of cancer at levels in the dietary 09:22 AM</p>

<p style="text-align: right;">Page 371</p> <p>1 studies that can be reached by these people</p> <p>2 taking the valsartan tablets within -- and I</p> <p>3 just read -- within six months. They can</p> <p>4 reach levels that are associated, from our</p> <p>5 epi studies, with increased risk of cancer. 09:22 AM</p> <p>6 And in the Hidajat study, for</p> <p>7 example, that has the 2nd, 3rd and 4th</p> <p>8 quadrants, which will estimate the amount of</p> <p>9 NDEA exposure that's associated with</p> <p>10 increased risk of 10 different types of 09:23 AM</p> <p>11 cancers.</p> <p>12 So in conjunction, as I mentioned</p> <p>13 using the Bradford Hill criteria, I detailed</p> <p>14 10 different types of tumors, and I can go</p> <p>15 through each of the tumor types, that based 09:23 AM</p> <p>16 on the animal data that -- of cancer</p> <p>17 causation, the mechanistic data, the</p> <p>18 epidemiology human data in these dietary</p> <p>19 studies to NDMA and the occupational study of</p> <p>20 NDMA that the rubber workers were exposed to, 09:23 AM</p> <p>21 that amount of NDMA -- the amount of NDMA in</p> <p>22 these human epi studies are higher than the</p> <p>23 levels that we're talking about with the</p> <p>24 valsartan people -- the people who took</p> <p>25 valsartan over a certain period of time. 09:24 AM</p>	<p style="text-align: right;">Page 373</p> <p>1 publications, it would be --</p> <p>2 Q. Sure. So if you'd like, you can</p> <p>3 take a minute and familiarize yourself with</p> <p>4 this because I've got some questions.</p> <p>5 A. Sure. 09:26 AM</p> <p>6 (Witness reviewing document.)</p> <p>7 Q. Okay?</p> <p>8 All right. Directing your</p> <p>9 attention to the third page into the article,</p> <p>10 the "Risk Assessment for NDMA." 09:26 AM</p> <p>11 You with me?</p> <p>12 A. Sorry. Yes.</p> <p>13 Q. And under Risk Assessment for</p> <p>14 NDMA, it opens with, "It seems reasonable to</p> <p>15 ask what constitutes a virtually safe dose 09:27 AM</p> <p>16 for NDMA, particularly as the substance is a</p> <p>17 known environmental contaminant that's</p> <p>18 routinely found in foodstuffs (including</p> <p>19 cured meat, dairy products and certain</p> <p>20 vegetables) and drinking water." 09:27 AM</p> <p>21 Do you see that, sir?</p> <p>22 A. Yes.</p> <p>23 Q. And if you look down that column,</p> <p>24 it references FDA's calculation using the</p> <p>25 TD 50 to get to the .096 milligrams per 09:27 AM</p>
<p style="text-align: right;">Page 372</p> <p>1 MR. FOWLER: Let's mark 18,</p> <p>2 please.</p> <p>3 (Exhibit 18, Short commentary on NDMA</p> <p>4 contamination of valsartan products, marked</p> <p>5 for identification.) 09:24 AM</p> <p>6 Q. Doctor, before you is Exhibit 18.</p> <p>7 It is an article by Dr. Snodin and Dr. Elder</p> <p>8 called "Short Commentary on NDMA</p> <p>9 Contamination of Valsartan products."</p> <p>10 I noted that you didn't include 09:24 AM</p> <p>11 this in your references, did you, sir?</p> <p>12 A. Let me check. Correct. I</p> <p>13 don't -- yes. Correct.</p> <p>14 Q. Have you seen this article before?</p> <p>15 Did it come up in any of your research? 09:25 AM</p> <p>16 A. So, as I mentioned before, I read</p> <p>17 over thousands, hundreds of publications --</p> <p>18 Q. Yes, sir.</p> <p>19 A. -- so I don't recall if I</p> <p>20 specifically had read this one. 09:25 AM</p> <p>21 Q. You don't recall whether you've</p> <p>22 seen this one, sir?</p> <p>23 A. Yeah, I've read a couple</p> <p>24 commentaries on NDMA. I don't remember if</p> <p>25 I -- you know, over reading hundreds of 09:25 AM</p>	<p style="text-align: right;">Page 374</p> <p>1 kilogram per day?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Then you see another risk</p> <p>4 assessment by Fitzgerald and Robinson. It's</p> <p>5 based on a comprehensive lifetime liver 09:27 AM</p> <p>6 cancer dose and that came up with an</p> <p>7 additional -- with a different range,</p> <p>8 correct, at .6 micrograms?</p> <p>9 MR. NIGH: Form objection.</p> <p>10 A. Yes. 09:28 AM</p> <p>11 BY MR. FOWLER:</p> <p>12 Q. Okay. If you look -- the last</p> <p>13 paragraph it says "Alternative</p> <p>14 risks-assessment metrics are permitted under</p> <p>15 the ICH M7 R1," and once -- it says "One such 09:28 AM</p> <p>16 alternative metric, sometimes called the</p> <p>17 'reference point' or 'point of departure,' is</p> <p>18 the BMDL 10."</p> <p>19 Do you see that? "Benchmark dose</p> <p>20 lower bound corresponding to a 10% increase 09:28 AM</p> <p>21 in tumor incidence."</p> <p>22 Do you see where I've read there,</p> <p>23 Doctor?</p> <p>24 A. Yes.</p> <p>25 Q. And using -- if you look to the 09:28 AM</p>

<p style="text-align: right;">Page 375</p> <p>1 next page, using that method, you see, "In 2 relation to NDMA, SCCS (Scientific Committee 3 on Consumer Safety) has determined a BMDL 10 4 of 27 micrograms -- 5 A. I'm sorry, I'm not following you. 09:29 AM 6 Where are you now? 7 Q. I'm sorry, sir. It's the second 8 column, partway down that first paragraph. 9 "In relation to NDMA, SCCS 10 (Scientific Committee on Consumer Safety) 09:29 AM 11 has determined the BMDL of 27 micrograms per 12 kilogram per day, which is equivalent to 1620 13 micrograms a day in a 60-kilogram person." 14 Q. Do you see that? 15 A. Yes. 09:29 AM 16 Q. And you've not done any BMDL 17 calculation on this data, have you, sir? 18 A. Correct. 19 Q. And you have no reason to dispute 20 the findings of the Scientific Committee on 09:29 AM 21 Consumer Safety, that 1620 micrograms a day 22 in a 60-kilogram consumer is a virtually safe 23 level? 24 MR. NIGH: Form objection. 25 A. I can't comment on the committee's 09:30 AM</p>	<p style="text-align: right;">Page 377</p> <p>1 type of -- yeah. 2 So for genotoxic carcinogens, what 3 I have seen the leading agencies rely on the 4 Peto et al. and other -- for genotoxic 5 carcinogens they use the TD 50. 09:31 AM 6 MR. FOWLER: Mark number 19, 7 please. 8 (Exhibit 19, SCCS, Opinion on Nitrosamines 9 and Secondary Amines in Cosmetic Products, 10 marked for identification.) 09:32 AM 11 MR. FOWLER: I didn't want to 12 knock your computer off if I slid those. 13 BY MR. FOWLER: 14 Q. Doctor, before you is the 15 Scientific Committee on Consumer Safety 09:32 AM 16 from -- that the Snowden article was 17 referencing. 18 You understand that this document 19 is what is referenced -- what was referenced 20 in the Snowden commentary? Correct, sir? 09:32 AM 21 A. Okay. 22 Q. Now, directing your attention to 23 page 21, do you see the table there, Table 3? 24 A. Yes. 25 Q. And the Table 3 is "Ranking the 09:32 AM</p>
<p style="text-align: right;">Page 376</p> <p>1 opinion, this committee. I would have to see 2 an assessment report. When I read reports 3 from the top leading agencies, such as IARC 4 NTP, EPA, EMA, U.S. Canada, these are 5 literally hundred-page documents that I have 09:30 AM 6 to go through very carefully. 7 What is clearly said is that the 8 FDA has used the TD 50 based on the linear 9 extrapolation that NDMA -- and they quote 10 from their report, in the EMA report -- that 09:30 AM 11 to minimize intake of NDMA and the FDA has 12 allowed a certain level, the 96 nanogram per 13 day. 14 So I have to say, overall, this is 15 a commentary, so it's not a peer-reviewed 09:30 AM 16 paper. I've cited several commentaries in my 17 report. However, we rely -- as I said 18 before, in IARC, which is one of the leading 19 cancer agencies that determines hazards 20 risk -- hazards, that does a chemical cause 09:31 AM 21 call cancer; and they say, in their 22 scientific reasoning, to rely on 23 peer-reviewed publications, so this is a 24 commentary, not a peer-reviewed publication. 25 And second, like I mentioned, this 09:31 AM</p>	<p style="text-align: right;">Page 378</p> <p>1 potencies of nitrosamines based on 2 carcinogenesis studies in rats (the data are 3 taken from the calculations presented in 4 Tables 1 through 7, see annexes." 5 And we looked at this table. And 09:33 AM 6 do you see NDMA on this table, sir? 7 A. Yes. 8 Q. And do you see the BMDL 10 9 calculation? 10 A. Yes. 09:33 AM 11 Q. And it says 0.27 milligrams per 12 kilogram body weight. 13 Do you see that? 14 A. Yes. 15 Q. And if you -- for a 60-kilogram 09:33 AM 16 person, you would multiply .027 times 60, 17 correct, sir? 18 A. As I mentioned before, it is 19 highly inappropriate, and I quoted WHO and 20 other agencies, to do any type of conversion 09:33 AM 21 between rodents and humans, because this 22 mechanism of action, this genotoxic 23 carcinogen is highly -- is virtually 24 identical in animals and humans 25 Q. Doctor, my question was math, 09:34 AM</p>

<p style="text-align: right;">Page 379</p> <p>1 actually.</p> <p>2 If you take 0.27 milligrams per</p> <p>3 kilogram and calculate that for a 60-kilogram</p> <p>4 person, that comes out to 1.6 milligrams,</p> <p>5 correct, which is 1620 micrograms. 09:34 AM</p> <p>6 Isn't that the right math, sir?</p> <p>7 A. Yes, I would agree with the math.</p> <p>8 Q. Yes, sir. And that's the math</p> <p>9 that Dr. Snodin and Elder did in their</p> <p>10 commentary for the 1620, correct? I just 09:34 AM</p> <p>11 want to --</p> <p>12 A. Yeah.</p> <p>13 Q. Okay. And according to this</p> <p>14 European commission, the scientific</p> <p>15 subcommittee, they have determined that a 09:34 AM</p> <p>16 daily exposure of 1620 micrograms is safe.</p> <p>17 That's what this says, isn't it,</p> <p>18 sir?</p> <p>19 MR. NIGH: Form objection.</p> <p>20 A. As I said before, I relied upon 09:35 AM</p> <p>21 the FDA, the EMA -- the EMA document -- the</p> <p>22 European Medical Association, which is from</p> <p>23 2020, this is a document from nine years ago.</p> <p>24 What I relied on are -- and also</p> <p>25 through my report, which has 583 references, 09:35 AM</p>	<p style="text-align: right;">Page 381</p> <p>1 /</p> <p>2 BY MR. FOWLER:</p> <p>3 Q. Doctor, returning your attention</p> <p>4 to this table, they also did a TD 50</p> <p>5 calculation. 09:37 AM</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. And their calculation was point --</p> <p>9 arrived at .0959 milligrams per kilogram,</p> <p>10 which, doing the math again, for a 09:37 AM</p> <p>11 60-kilogram person, that would be 5.7</p> <p>12 milligrams or 5700 micrograms.</p> <p>13 Isn't that -- would I be correct</p> <p>14 in that math, sir?</p> <p>15 MR. FOWLER: Form objection. 09:37 AM</p> <p>16 BY MR. FOWLER:</p> <p>17 Q. And I am a lawyer, so you better</p> <p>18 check it.</p> <p>19 A. Yes. Like I said before, it's</p> <p>20 really more the point of this committee, the 09:37 AM</p> <p>21 Scientific Committee on Consumer Safety, who</p> <p>22 have their opinion on nitrosamine secondary</p> <p>23 amines. They're using a different</p> <p>24 methodology that, currently, that the FDA,</p> <p>25 that IARC, the EMA and Canada are using the 09:37 AM</p>
<p style="text-align: right;">Page 380</p> <p>1 and I -- in science we don't decide something</p> <p>2 based on one paper or one commentary.</p> <p>3 What IARC decides, in my opinion,</p> <p>4 that NDMA and NDEA can cause human cancer, is</p> <p>5 based on the totality of the evidence that I 09:35 AM</p> <p>6 have just presented, the human epi data.</p> <p>7 And some of these studies that I'm</p> <p>8 citing are at 2019. This report is 2011,</p> <p>9 nine years ago. Hidajat was 2019. They</p> <p>10 didn't have the evidence -- they didn't have 09:36 AM</p> <p>11 the totality of what's known here.</p> <p>12 And second, what I relied on, the</p> <p>13 2002 WHO, as I said before, that it is</p> <p>14 inappropriate to do any type of conversion</p> <p>15 between animals and humans. 09:36 AM</p> <p>16 And the EMA, the IARC, the FDA,</p> <p>17 the EPA, the NTP, U.S. Canada, so six of the</p> <p>18 leading agencies, which I've documented in my</p> <p>19 report, have all said that this exposure</p> <p>20 should be minimized, limited, or in the case 09:36 AM</p> <p>21 of the FDA said there's a certain amount</p> <p>22 that's allowed.</p> <p>23 THE REPORTER: Or in the case of?</p> <p>24 THE WITNESS: The FDA, which is</p> <p>25 said 96 nanogram per day. 09:36 AM</p>	<p style="text-align: right;">Page 382</p> <p>1 TD 50, based on a linear approach, that the</p> <p>2 genotoxic carcinogen can cause cancer.</p> <p>3 And as far as I'm aware, the FDA</p> <p>4 and the EMA and Canada don't use this type of</p> <p>5 conversion. 09:38 AM</p> <p>6 Q. They use TD 50, according to you,</p> <p>7 right?</p> <p>8 A. No, the BMDL.</p> <p>9 Q. Yes, sir. But they use the TD 50?</p> <p>10 A. Yes, they use the TD 50. 09:38 AM</p> <p>11 And as I've calculated in my</p> <p>12 report and what they've said, the permitted</p> <p>13 allowance -- the acceptable intake is 96</p> <p>14 nanograms of NDMA per day or 26.5 nanograms</p> <p>15 of NDEA per day. 09:38 AM</p> <p>16 Q. And according to this</p> <p>17 determination by the SCCS, the TD 50 would</p> <p>18 allow for 5.7 milligrams per day in a</p> <p>19 60-kilogram human.</p> <p>20 That's what this document says, 09:39 AM</p> <p>21 correct?</p> <p>22 A. I don't see -- where are you --</p> <p>23 Q. The TD 50 column, sir. .095</p> <p>24 milligrams per kilogram multiplied by 60 is</p> <p>25 5.74, correct? 09:39 AM</p>

<p style="text-align: right;">Page 383</p> <p>1 A. Where do they say 574?</p> <p>2 Q. It's the math, sir.</p> <p>3 A. I'm not following.</p> <p>4 Q. The TD 50 calculation in this</p> <p>5 European commission document, at .095, if you 09:39 AM</p> <p>6 multiply that by 60 for a 60-kilogram human,</p> <p>7 that comes out to 5.7 milligrams per</p> <p>8 kilogram, correct? Is that math right? Yeah</p> <p>9 MR. NIGH: Form objection.</p> <p>10 A. I would -- as I said, when the FDA 09:39 AM</p> <p>11 did the conversion on the TD 50 -- of</p> <p>12 acceptable index with the TD 50, it comes out</p> <p>13 to 96 nanogram per day.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. Right. That's what FDA's 09:40 AM</p> <p>16 calculation was.</p> <p>17 And this TD 50 calculation states</p> <p>18 that it's actually 5.7 milligrams or 5700</p> <p>19 micrograms per day is a virtually safe dose,</p> <p>20 according to the European commission. 09:40 AM</p> <p>21 MR. NIGH: Form objection.</p> <p>22 A. I'm not following that.</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. Okay. You can set this aside.</p> <p>25 THE REPORTER: 20. 09:41 AM</p>	<p style="text-align: right;">Page 385</p> <p>1 parts per million (resulting in a daily dose</p> <p>2 of approximately 5 milligrams per kilogram)</p> <p>3 for 16 days gave rise to significant increase</p> <p>4 in hepatocyte proliferation, whereas no</p> <p>5 increase was observed in animals exposed to 09:42 AM</p> <p>6 threefold lower concentration of NDMA."</p> <p>7 Do you see that, sir?</p> <p>8 A. Yes.</p> <p>9 Q. And according to this study,</p> <p>10 they're at a lower dose, there was 09:43 AM</p> <p>11 no increase in hepatocyte proliferation.</p> <p>12 That's what they found, correct,</p> <p>13 sir?</p> <p>14 A. Correct.</p> <p>15 Q. And that would indicate a 09:43 AM</p> <p>16 threshold level at which no adverse effect of</p> <p>17 hepatocyte proliferation was observed,</p> <p>18 correct?</p> <p>19 A. No. As I mentioned before, in</p> <p>20 cancer, the 10 key characteristics, you can't 09:43 AM</p> <p>21 isolate each one and say there's a threshold</p> <p>22 effect. So proliferation is one of -- one --</p> <p>23 it's key characteristic 10, and it's not even</p> <p>24 the only key characteristic. There's blood</p> <p>25 vessels, angiogenesis, there's cell death, 09:43 AM</p>
<p style="text-align: right;">Page 384</p> <p>1 MR. FOWLER: 20. Thank you.</p> <p>2 (Exhibit 20, DNA adducts, mutant frequencies</p> <p>3 and mutation spectra in lacZ transgenic mice</p> <p>4 treated with N-nitrosodimethylamine, marked</p> <p>5 for identification.) 09:41 AM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. Doctor, before you is Exhibit 20.</p> <p>8 This is an article, 1998 DNA adducts, mutant</p> <p>9 frequencies and mutation spectra in certain</p> <p>10 transgenic mice treated with NDMA, correct? 09:41 AM</p> <p>11 A. Yes.</p> <p>12 Q. And this is an article that you</p> <p>13 cite in your report, correct, sir? So you're</p> <p>14 familiar with it?</p> <p>15 A. Yes. 09:41 AM</p> <p>16 Q. Okay. And directing your</p> <p>17 attention to page 735, the second column, you</p> <p>18 see the sentence begins with "While." It's</p> <p>19 about 10 lines down.</p> <p>20 "While no" systemic -- "While no 09:42 AM</p> <p>21 systematic study of the effects of dose and</p> <p>22 time on toxicity-induced cell proliferation</p> <p>23 has been recorded, it is noted that the</p> <p>24 treatment of C3H mice with NDMA dissolved in</p> <p>25 their drinking water at concentration of 30 09:42 AM</p>	<p style="text-align: right;">Page 386</p> <p>1 apoptosis. You can't conclude, just because</p> <p>2 there's no increase in proliferation, that</p> <p>3 there's no threshold.</p> <p>4 When we determine a threshold in</p> <p>5 animal experiments, such as Peto and 09:44 AM</p> <p>6 Terracini, I would have to see the tumor</p> <p>7 curve and the doses.</p> <p>8 Q. Doctor, my question was specific</p> <p>9 to this finding.</p> <p>10 This was a threshold level that 09:44 AM</p> <p>11 these scientists reported below which there</p> <p>12 was not the adverse effect that they were</p> <p>13 studying, correct.</p> <p>14 MR. NIGH: Hold on. Form</p> <p>15 objection. Object to the colloquy. 09:44 AM</p> <p>16 A. I'm not sure I'm -- are you saying</p> <p>17 no increase in proliferation is --</p> <p>18 THE REPORTER: I'm sorry, Doctor,</p> <p>19 I didn't get that.</p> <p>20 A. I don't understand the question. 09:44 AM</p> <p>21 BY MR. FOWLER:</p> <p>22 Q. Let's look at the next sentence,</p> <p>23 sir.</p> <p>24 "Furthermore, Doolittle et al.</p> <p>25 reported that seven daily treatments of CD 09:44 AM</p>

<p style="text-align: right;">Page 387</p> <p>1 mice with 4 milligrams per kilogram NDMA gave</p> <p>2 rise to a toxicity-associated increase in</p> <p>3 hepatocyte replication, whereas a similar</p> <p>4 treatment of 2 kilograms per kilogram had no</p> <p>5 detectable effect." 09:45 AM</p> <p>6 Did I read that correctly?</p> <p>7 A. Correct.</p> <p>8 Q. And does that also provide</p> <p>9 evidence that in that study there was a</p> <p>10 threshold level below which there was no 09:45 AM</p> <p>11 detectable effect?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. I would have to see what the</p> <p>14 effect is.</p> <p>15 BY MR. FOWLER: 09:45 AM</p> <p>16 Q. Okay. Do you agree that when the</p> <p>17 authors report no effect at 2 milligrams</p> <p>18 compared to 4 milligrams, they are -- that is</p> <p>19 defining a threshold level in that study?</p> <p>20 MR. NIGH: Form objection. 09:45 AM</p> <p>21 A. So the readout we use is tumor</p> <p>22 induction. So I just have to see what the</p> <p>23 readout here IS, had no detectable effect.</p> <p>24 Because they said toxicity</p> <p>25 increase in hepatocyte replication. 09:45 AM</p>	<p style="text-align: right;">Page 389</p> <p>1 oral doses of 1 milligram per kilogram NDMA</p> <p>2 did not induce any significant cell</p> <p>3 proliferation in hepatocytes of Big Blue</p> <p>4 mice."</p> <p>5 Do you see that, sir? 09:47 AM</p> <p>6 A. Yes.</p> <p>7 Q. So, again, they're reporting a</p> <p>8 level of NDMA that did not cause the effect</p> <p>9 that they were studying.</p> <p>10 Can we agree that's what that 09:47 AM</p> <p>11 study reports?</p> <p>12 A. Correct. They were studying the</p> <p>13 proliferation of hepatocytes in C57 mice.</p> <p>14 Q. "Based on these data," it states,</p> <p>15 "it appears that little if any hepatocyte 09:47 AM</p> <p>16 proliferation would be induced by 10 daily</p> <p>17 doses of the 1 milligram per kilogram of NDMA</p> <p>18 as employed in our study, where it would have</p> <p>19 been after the highest single dose employed,</p> <p>20 i.e., 10 milligrams per kilogram." 09:48 AM</p> <p>21 Do you see that, sir?</p> <p>22 A. Yes.</p> <p>23 Q. And if we break that down, that is</p> <p>24 reporting that a single dose at 10 milligrams</p> <p>25 per kilogram induced an effect that the same 09:48 AM</p>
<p style="text-align: right;">Page 388</p> <p>1 Hepatocyte replication, as I mention in the</p> <p>2 key characteristics of cancer, that's that</p> <p>3 not a readout. We don't use proliferation or</p> <p>4 replication as a readout of threshold doses</p> <p>5 when you -- the term, does a chemical cause 09:46 AM</p> <p>6 cancer, and Peto used 4,000 rats with 16</p> <p>7 different doses with about 30 males each, 30</p> <p>8 females each, one of the largest chemical</p> <p>9 carcinogen assays in the field. In fact,</p> <p>10 that experiment, which we used to determine 09:46 AM</p> <p>11 the linear threshold -- the no threshold</p> <p>12 dose, that is a classic study because of the</p> <p>13 amount and number of animals.</p> <p>14 To say that -- I'm still not</p> <p>15 understanding your question. 09:46 AM</p> <p>16 Q. I'll ask it again, sir.</p> <p>17 For the effect of NDMA that was</p> <p>18 being studied by Doolittle, they observed an</p> <p>19 effect at 4 milligrams that they did not</p> <p>20 observe at 2 milligrams. That's what this 09:47 AM</p> <p>21 reports, correct, sir?</p> <p>22 A. Correct.</p> <p>23 Q. Okay. Thank you.</p> <p>24 And looking at the next sentence</p> <p>25 "Finally, Suzuki et al. reported that 5 daily 09:47 AM</p>	<p style="text-align: right;">Page 390</p> <p>1 10 milligrams spread out over 10 days at one</p> <p>2 milligram did not produce.</p> <p>3 That's what this means, isn't it,</p> <p>4 sir?</p> <p>5 A. Yes. But, as I've said, using the 09:48 AM</p> <p>6 hepatocyte proliferation as a readout to</p> <p>7 determine a threshold dose in animals, that's</p> <p>8 very misleading. Like I said, in the key</p> <p>9 characteristics of cancer, proliferation,</p> <p>10 apoptosis, angiogenesis, chemical -- genomic 09:48 AM</p> <p>11 instability, electrophilic metabolite</p> <p>12 activation, oxidative stress, inflammation.</p> <p>13 The fact that NDMA and NDEA can</p> <p>14 cause cancer in animals and the Peto study</p> <p>15 that we base the threshold -- the no 09:49 AM</p> <p>16 threshold on is 4,080 rats and the readout is</p> <p>17 cancer induction.</p> <p>18 The mechanism of cancer</p> <p>19 induction -- proliferation and hepatocyte</p> <p>20 proliferation is just one marker of how a 09:49 AM</p> <p>21 cancer can grow. There are plenty of</p> <p>22 mechanisms how a cancer can grow and have no</p> <p>23 effect on proliferation.</p> <p>24 NDMA can cause cancer through</p> <p>25 other mechanisms besides proliferation, and 09:49 AM</p>

<p style="text-align: right;">Page 391</p> <p>1 as I mentioned in my report with the key 2 characteristics. In fact, NDMA and NDEA can 3 exhibit 9 of the 10 key characteristics. 4 And that's why in science it's 5 very important to put the context of what a 09:49 AM 6 finding is in the context of the field. We 7 know that this is a carcinogen that causes 8 cancer in multiple species, multiple ways of 9 administration, multiple sites. So we know 10 that the NDMA and NDEA causes cancer. 09:50 AM 11 The mechanism can depend on, as I 12 mention -- and this is very important that 13 IARC has stressed. There are multiple 14 mechanisms of carcinogens. There's not only 15 just proliferation, apoptosis, cell death. 09:50 AM 16 A genotoxic carcinogen such as 17 NDMA can trigger -- that metabolic activation 18 can trigger multiple steps. And that as I 19 mentioned yesterday, many of these key 20 characteristics, such as oxidative stress, 09:50 AM 21 inflammation, and apoptosis are related to 22 that induction of the DNA adducts and the 23 mutagenesis and the genotoxicity. 24 So proliferation, which is the one 25 readout here, is only one potential mechanism 09:51 AM</p>	<p style="text-align: right;">Page 393</p> <p>1 of dose threshold in cancer causation. In 2 fact, that's -- mutagenesis alone doesn't 3 mean a chemical will cause cancer. 4 BY MR. FOWLER: 5 Q. Okay. 09:52 AM 6 A. It's an important step. And, as I 7 mentioned, that's why IARC has stressed there 8 10 key characteristics, and mutagenesis DNA 9 instability is only one part of it. So not 10 all chemicals that induce mutagenesis cause 09:52 AM 11 cancer. 12 But in this case, NDMA and NDEA, 13 we have the overwhelming evidence that this 14 is a potent carcinogen in the animals and a 15 potent carcinogen in the epi studies and in 09:53 AM 16 the mechanism. 17 So what's important in science, if 18 we put the context of this paper into the 19 context of the overwhelming evidence in the 20 field of 60 years of literature, and I cited 09:53 AM 21 over 500 publications, and as I said before, 22 for threshold, relying on Peto and Terracini 23 and others, these are the studies where, 24 actually, instead of using proliferation or 25 mutagenesis as a readout, they use the cancer 09:53 AM</p>
<p style="text-align: right;">Page 392</p> <p>1 of the cancer causation. 2 Q. And this article that you cited 3 that we're talking about is peer reviewed in 4 the Journal of Carcinogenesis, correct, sir? 5 A. Correct. 09:51 AM 6 Q. And turning your attention to the 7 conclusion on page 737, top of the page, 8 second column, it states, "This suggests that 9 toxicity-induced liver cell proliferation may 10 play an important role in determining NDMA 09:51 AM 11 mutagenesis in the liver and that 12 extrapolation of NDMA-mediated mutagenic 13 effects to low dose levels should not be 14 based on the assumption of dose linearity, 15 even if dose is expressed in terms of DNA 09:51 AM 16 damage." 17 Do you see that, sir? 18 A. Yes. 19 Q. And in this article that you 20 cited, that is suggesting that their finding 09:52 AM 21 supports a nonlinear dose relationship at low 22 levels. That's what this says, isn't it? 23 MR. NIGH: Form objection. 24 A. So in one paper focused on 25 mutations, mutations aren't a determination 09:52 AM</p>	<p style="text-align: right;">Page 394</p> <p>1 induction as a readout. 2 And in the case of Peto, that 3 no-dose threshold is in the linear approach, 4 which is accepted and approved by the FDA, 5 the EMA, IARC, NTP, EPA, that that was based 09:53 AM 6 on 4,080 rats. 7 And not only is that study used in 8 the nitrosamine literature, in the chemical 9 carcinogenesis field, it is a classic study 10 that is applicable to many carcinogens, not 09:54 AM 11 just NDMA and NDEA. 12 It's very unusual for a study such 13 as Peto to have 4,000 animals, 16 groups, 30 14 female rats in each group, and they let the 15 rats live out to their lifetime, which is 09:54 AM 16 very important. To determine a dose 17 threshold, you want to see the entire 18 readout -- of the readout of the tumor 19 induction, which in Peto they let the animals 20 go out all the way. 09:54 AM 21 So, as I said, in science we use 22 an overwhelming synthesis of not only the 23 animal studies, which I mention before, the 24 chemical carcinogenesis bioassay, that assay 25 is the single goal standard to start the 09:55 AM</p>

<p style="text-align: right;">Page 395</p> <p>1 process to ask the question does a chemical 2 cause cancer.</p> <p>3 But then we use the mechanistic 4 studies that I've detailed in my report, the 5 10 key characteristics that use animal 09:55 AM 6 tissue, rodent tissue, and then use human 7 tissue; and then using the epidemiology, the 8 human studies with people, and together that 9 that's how we determine does a chemical cause 10 cancer. And in this case, NDMA and NDEA 09:55 AM 11 cause human cancer.</p> <p>12 Q. Doctor, you've stated at one point 13 here this morning that we base no threshold 14 on Peto.</p> <p>15 Do you recall stating that? 09:55 AM</p> <p>16 A. Yes.</p> <p>17 Q. Who's the "we" in that situation?</p> <p>18 A. So let me say -- when I say "we," 19 the field -- so as I mentioned yesterday, 20 there are leading agencies, such as IARC, 09:56 AM 21 that assemble leading scientists in the 22 field, who will go through, in a very 23 rigorous, systematic way, the four lines of 24 evidence, such as animal data, mechanistic 25 data, human tissues, epidemiology data, and 09:56 AM</p>	<p style="text-align: right;">Page 397</p> <p>1 assumption by him in that study with regard 2 to low doses, correct?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. Peto noticed the -- the lowest 5 dose that they used in the liver cancer 09:58 AM 6 studies, they saw cancer, and then they -- 7 and all those doses that they show cancer, 8 then they use -- other people can use and 9 they can use a linear extrapolation to 10 backtrack and say at a certain dose you get 09:58 AM 11 cancer.</p> <p>12 So the important part of Peto 13 is -- and Peto, as I said before, had 60 14 animals per group. And they let the rats 15 live out, and they showed that there -- at 09:58 AM 16 every dose they use, in the liver cancer 17 studies, cause cancer. And then we use a 18 linear extrapolation, when I say "we," the 19 field, uses a linear extrapolation to 20 calculate the no-dose threshold. 09:58 AM</p> <p>21 Q. So, Doctor, you believe that the 22 Peto 1991 two-year cancer bioassay has good, 23 reliable data?</p> <p>24 A. In every -- that is one of the 25 classic studies that people use, yes. 09:59 AM</p>
<p style="text-align: right;">Page 396</p> <p>1 they will determine -- they will do a 2 suggestion of the hazard analysis.</p> <p>3 And then, as I mentioned, leading 4 agencies, such as the regulatory agencies, 5 will look at that and determine the risk. 09:56 AM</p> <p>6 Q. Doctor, I'm talking about Peto and 7 only Peto for the next few minutes. Okay?</p> <p>8 You made a statement that we base 9 no threshold on Peto. Are you suggesting 10 that the Peto data supports no threshold, 09:57 AM 11 sir?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. So if you look at the liver cancer 14 that the NDMA -- which the target in NDMA is 15 liver cancer, so if you look at the liver 09:57 AM 16 cancer studies, so one part per million was 17 associated with 25 percent incidence of 18 cancer; and if you extrapolate with the 19 linear curve, then that 0.2 part per million 20 was less than -- there's still a percent with 09:57 AM 21 the liver cancer studies in Peto that you see 22 no threshold, even a small dose is 23 extrapolated to cause cancer.</p> <p>24 Q. Peto did not have data on the low 25 dose, it was a calculation -- it was an 09:57 AM</p>	<p style="text-align: right;">Page 398</p> <p>1 Q. I'm just asking a simple question.</p> <p>2 A. Yes.</p> <p>3 Q. Yes, the data is reliable and you 4 rely on Peto?</p> <p>5 A. Yes. 09:59 AM</p> <p>6 Q. And it is your contention that the 7 Peto data supports your opinion that there's 8 no threshold level?</p> <p>9 A. With liver cancer, with NDMA, yes, 10 that there -- like I said before, that one 09:59 AM 11 part per million was associated -- even at 12 the lowest dose they used, they saw liver 13 cancer.</p> <p>14 What's important also, as I cited 15 583 papers in my report, I don't only rely on 09:59 AM 16 Peto. So Terracini et al., 1967, when they 17 gave 2 part per million, 5 part per million, 18 all the animals were -- got cancer. So NDMA 19 could cause cancer at every dose. And I 20 cited, in liver cancer, at least 32 10:00 AM 21 publications, and I cited multiple 22 publications.</p> <p>23 So while Peto is the largest 24 study, with 4,080 rats, and NDMA cause liver 25 cancer at every dose, I don't rely only on 10:00 AM</p>

<p style="text-align: right;">Page 399</p> <p>1 Peto. So Terracini, 1967, and other studies 2 in my report, also show -- are consistent 3 with a linear dose response that at every 4 dose in that study, for example, Terracini 5 1967, 2 part per million, 5 part per million, 10:00 AM 6 10 part per million all cause cancer. 7 MR. NIGH: Mr. Fowler, we've been 8 going for over a hour. How much longer 9 do you want to go before a break? 10 MR. FOWLER: We'll stop. Whenever 10:01 AM 11 you do that, I'm happy to stop because 12 it breaks the flow, so we'll take a 13 break now. 14 MR. NIGH: When I ask you a 15 question how much longer you we want to 10:01 AM 16 go? 17 MR. FOWLER: Yeah. 18 MR. NIGH: Okay. 19 THE VIDEOGRAPHER: The time is 10 20 o'clock we're off the record. 10:01 AM 21 (Recess taken at 10:01 a.m. to 10:17 a.m.) 22 THE VIDEOGRAPHER: The time is 23 10:16. We're back on the record. 24 BY MR. FOWLER: 25 Q. Doctor, a couple housekeeping 10:17 AM</p>	<p style="text-align: right;">Page 401</p> <p>1 make this number 21. 2 (Exhibit 21, Rule 26 Expert Report of Dipak 3 Panigrahy, MD, marked for identification.) 4 MR. FOWLER: And here's eight 5 pounds that we don't have to carry back, 10:19 AM 6 Counsel. Two copies. 7 Now I'm going to mark Exhibit 22, 8 please. 9 (Exhibit 22, Dose and Time Relationships for 10 Tumor Induction in the Liver and Esophagus of 10:20 AM 11 4080 Inbred Rats by Chronic Ingestion of 12 N-Nitrosodiethylamine or 13 N-Nitrosodimethylamine, marked for 14 identification.) 15 BY MR. FOWLER: 10:20 AM 16 Q. Sir, Exhibit 22 is one of the two 17 Peto articles on his two-year bioassay, 18 correct, sir? 19 A. Correct. 20 Q. And this is the study that you've 10:20 AM 21 been referencing in this deposition with 22 regard to your opinion on they're not being a 23 threshold, correct, sir? 24 A. Correct. One of the articles, 25 yes. 10:20 AM</p>
<p style="text-align: right;">Page 400</p> <p>1 matters before I get in trouble with madam 2 court reporter. 3 The articles that you brought 4 yesterday that we had a placeholder to put 5 Exhibit 4 onto. You've got those today as 10:17 AM 6 well, sir? 7 A. Are you talking about the ones I 8 had yesterday? 9 Q. Yes, sir. So I'd like to mark 10 those as Exhibit 4. And what we'll do at 10:17 AM 11 lunch, and I'll stop talking in a second, at 12 lunch we'll make a copy of the new 17 and 13 then this so that you can have your articles 14 back. 15 A. Yeah, I actually have PDFs. I 10:17 AM 16 mean I can -- if it's easier. 17 Q. Your counsel will want you to have 18 them back because they've got your highlight. 19 I'm happy to keep them. Let's mark it 4. 20 (Exhibit 4, marked on 9/9/21.) 10:18 AM 21 Q. I'm returning these to you, sir. 22 A. Thank you. 23 Q. And the second housekeeping matter 24 is, I want to mark your report as an exhibit. 25 I'd be in trouble if I didn't do that. Let's 10:18 AM</p>	<p style="text-align: right;">Page 402</p> <p>1 Q. And directing your attention to 2 the -- the bottom page number is 6463, and 3 I'm going to direct your attention to 4 Table 7, it's the landscape, the horizontal 5 table. 10:21 AM 6 Are you with me, sir? 7 A. Yes. 8 Q. Now let's look at -- well, first 9 of all, do you agree that this table reflects 10 the numbers of liver cancer -- the level of 10:21 AM 11 liver cancer that occurred in the various 12 doses that were provided to these mice, 13 correct? 14 A. Yes. They were rats. Rats. 15 Q. Rats. Sorry. 10:21 AM 16 And the first treatment group, 17 number 1, is the control group, right? 18 A. Correct. 19 Q. Bear with me a second, Doctor. 20 Okay. What we see are the 10:22 AM 21 treatment groups that you referred to. 22 There's 15 treatment groups below that, 23 correct. 24 A. Correct. 25 Q. And the control group demonstrated 10:22 AM</p>

<p style="text-align: right;">Page 403</p> <p>1 10 liver cell -- 10 liver tumors as there 2 background rate, if you will, the control 3 group had 10 liver tumors develop, correct? 4 MR. NIGH: Form objection. 5 A. Correct. 10:23 AM 6 BY MR. FOWLER: 7 Q. And when we look at the first dose 8 given at .001, there were four liver tumors 9 reported in that group, correct? 10 A. Correct. 10:23 AM 11 Q. And four is less than 10? 12 A. Yes. 13 Q. And you cannot draw any conclusion 14 that the four tumors seen at the lowest dose 15 are NDMA-related, because they're less than 10:23 AM 16 the background rate of 10 tumors in untreated 17 rats, correct? Doctor? 18 A. Correct. 19 Q. And the second level dose, 20 at .003, only three tumors were observed in 10:24 AM 21 that group. 22 And three is less than 10 in the 23 control group, correct? 24 A. Correct. 25 Q. And you cannot attribute the 10:24 AM</p>	<p style="text-align: right;">Page 405</p> <p>1 A. So what Peto does is that one part 2 per million there's an increase in the 3 observed-to-expected ratio. They compiled 4 what's the observed-to-expected ratio and 5 that -- it increases above the one part per 10:25 AM 6 million. 7 Q. You can set that aside, sir. 8 MR. FOWLER: Exhibit 23, please. 9 (Exhibit 23, Risk Assessment of 10 N-nitrosodimethylamine formed Endogenously 10:26 AM 11 after Fish-with-Vegetable Meals, marked for 12 identification.) 13 BY MR. FOWLER: 14 Q. Before you, sir, is Exhibit 23. 15 This is a 2010 article in Toxicological 10:26 AM 16 Sciences. 17 Is that a peer-reviewed journal, 18 sir. 19 A. Correct. 20 Q. And the article is titled "Risk 10:27 AM 21 Assessment of NDMA formed Endogenously After 22 Fish-with-Vegetable Meals," right? 23 A. Correct. 24 Q. Doctor, if you turn -- first of 25 all -- I'm sorry. I'll stop the colloquy. 10:27 AM</p>
<p style="text-align: right;">Page 404</p> <p>1 tumors that were observed in treatment group 2 3 to NDMA because they were less than the 3 background rate of untreated rats, correct? 4 Sir, I'm still on Table 7. 5 A. Yeah, they're -- 10:24 AM 6 Q. And I could continue these 7 questions all the way through treatment group 8 9 that exhibited 7 liver tumors. 9 Seven is still less than the 10 control group, correct? 10:25 AM 11 A. Yes. 12 Q. And it's not until the 10th group 13 at .109 that we actually see a greater 14 incidence of liver tumors than the control 15 group, right? 10:25 AM 16 A. Correct. 17 Q. So you cannot draw any conclusion 18 that at the low doses of NDMA given to the 19 first eight treatment groups, that the liver 20 tumors observed were the result of NDMA; 10:25 AM 21 isn't that true? 22 A. So what -- 23 Q. I'm sorry? 24 A. Correct. 25 Q. Thank you. 10:25 AM</p>	<p style="text-align: right;">Page 406</p> <p>1 First of all, on the first page, 2 second column, Doctor, you see the statement 3 "Endogenous formation of NDMA may amount to 4 27 to 34 micrograms, whereas the direct, 5 exogenous intake of NDMA in the Netherlands" 10:27 AM 6 anyway, "is estimated to be lower, around .1 7 micrograms per day." 8 Did I read that relatively 9 correctly? 10 A. Correct. You read it correctly. 10:28 AM 11 Q. Thank you. 12 And Krul, that's one of the 13 articles we looked at yesterday. 14 Do you recall that, sir? 15 A. Yes. 10:28 AM 16 Q. Now, turning your attention to the 17 third page of this article. It's article 18 page 325 at the top corner. 19 Are you with me, sir? 20 A. Yes. 10:28 AM 21 Q. Do you see a section called 22 "Dose-Response Assessment"? 23 A. Yes. 24 Q. And do you recognize the Peto 25 studies that are referred to there? 10:28 AM</p>

<p style="text-align: right;">Page 407</p> <p>1 A. Yes.</p> <p>2 Q. So can we agree that this study</p> <p>3 used the Peto data in the analysis that we're</p> <p>4 going to talk about here?</p> <p>5 A. Well, first I would say the 10:28 AM</p> <p>6 sentence that you said -- like I said before,</p> <p>7 there's no reliable way to measure endogenous</p> <p>8 NDMA. So the sentence that you're quoting</p> <p>9 here, they're quoting Krul 2004 --</p> <p>10 Q. Yep. 10:29 AM</p> <p>11 A. -- and there's currently no</p> <p>12 reliable way to measure endogenous NDMA.</p> <p>13 Q. I understand. I just added that</p> <p>14 again because this is -- in a peer-reviewed</p> <p>15 journal these type of facts are checked, 10:29 AM</p> <p>16 right? Doctor?</p> <p>17 A. The article is under -- yes.</p> <p>18 Q. In a peer-reviewed journal,</p> <p>19 statements like "endogenous formation of NDMA</p> <p>20 may amount to 27 to 34 micrograms," is 10:29 AM</p> <p>21 checked by peer reviewers; correct?</p> <p>22 A. That statement relies on in vitro</p> <p>23 assay to quantify an amount endogenous and</p> <p>24 they say may amount to.</p> <p>25 There's not -- this is in 2010. 10:29 AM</p>	<p style="text-align: right;">Page 409</p> <p>1 is, you would agree, then, that the amount</p> <p>2 detected in the valsartan tablets is less</p> <p>3 than the amount produced endogenously, under</p> <p>4 that assumption?</p> <p>5 MR. NIGH: Form objection. 10:31 AM</p> <p>6 BY MR. FOWLER:</p> <p>7 Q. Right?</p> <p>8 MR. NIGH: Form objection.</p> <p>9 BY MR. FOWLER:</p> <p>10 Q. I'll withdraw the question. I'm 10:31 AM</p> <p>11 really not here to talk more about</p> <p>12 endogenous, so let's --</p> <p>13 A. Okay.</p> <p>14 Q. I understand your position, and</p> <p>15 we're all fine on that. 10:31 AM</p> <p>16 Back to the dose question, Doctor.</p> <p>17 You agree that this -- that this</p> <p>18 study used the Peto bioassay data. That's</p> <p>19 what the statement says, right?</p> <p>20 A. Correct. 10:31 AM</p> <p>21 Q. And it states "We used this study</p> <p>22 for dose-response analysis related to chronic</p> <p>23 exposure," correct?</p> <p>24 A. Yes.</p> <p>25 Q. "Health-based limit values for 10:31 AM</p>
<p style="text-align: right;">Page 408</p> <p>1 We know in 2020 there's not an accurate way</p> <p>2 to measure the endogenous NDMA. They're just</p> <p>3 suggesting that may account to 27 to 34</p> <p>4 microgram, and they're citing a paper that</p> <p>5 used modeling, didn't measure the NDMA using 10:30 AM</p> <p>6 a biologically accurate way to measure that</p> <p>7 NDMA.</p> <p>8 Q. Yeah. Yes, Doctor.</p> <p>9 And assuming, Doctor,</p> <p>10 hypothetically, please, because you're an 10:30 AM</p> <p>11 expert, I can ask you this, assuming</p> <p>12 hypothetically that there is 27 to 34</p> <p>13 micrograms a day produced endogenously, you</p> <p>14 would agree that that amount exceeds the</p> <p>15 level of NDMA detected in the affected 10:30 AM</p> <p>16 valsartan tablets, correct?</p> <p>17 A. That's a hypothetical situation.</p> <p>18 We can't -- we don't have an accurate,</p> <p>19 biological method to measure endogenous NDMA.</p> <p>20 Q. Doctor, I'm asking you a 10:30 AM</p> <p>21 hypothetical question.</p> <p>22 For purposes of this question,</p> <p>23 assume that the body produces 34 micrograms a</p> <p>24 day.</p> <p>25 And my question on that assumption 10:31 AM</p>	<p style="text-align: right;">Page 410</p> <p>1 NDMA-induced carcinogenicity have been</p> <p>2 derived in the past (e.g., 27 to 186</p> <p>3 nanograms per kilogram)."</p> <p>4 Do you see that, sir?</p> <p>5 A. Yes. 10:32 AM</p> <p>6 Q. And are you going to dispute that</p> <p>7 prior studies have found 186 nanograms per</p> <p>8 kilogram to be an acceptable level, at least</p> <p>9 according to this article?</p> <p>10 MR. NIGH: Form objection. 10:32 AM</p> <p>11 A. As I said before, I'm going</p> <p>12 according to the FDA's 96 nanogram per day</p> <p>13 acceptable index.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. Okay. 10:32 AM</p> <p>16 A. That's in the year -- this paper</p> <p>17 is 10 years ago. So I'm going with the</p> <p>18 current FDA acceptable index of 96 nanogram</p> <p>19 per day for the NDMA.</p> <p>20 Q. Doctor, you relied on roughly 300 10:32 AM</p> <p>21 articles before the year 2000, right?</p> <p>22 A. Correct.</p> <p>23 Q. Okay. So are you really going --</p> <p>24 never mind. Withdrawn.</p> <p>25 Turn your attention to page 327, 10:33 AM</p>

<p style="text-align: right;">Page 411</p> <p>1 sir.</p> <p>2 And, by the way, you did not</p> <p>3 include this Zeilmaker study in your reliance</p> <p>4 material, did you?</p> <p>5 A. I believe it wasn't in my 10:33 AM</p> <p>6 reference list.</p> <p>7 Q. I believe it wasn't either.</p> <p>8 And my question would be, you</p> <p>9 know, since you really liked the Peto data,</p> <p>10 why didn't you include a study that -- this 10:33 AM</p> <p>11 study that relies on that Peto data? Why</p> <p>12 didn't you include this?</p> <p>13 MR. NIGH: Form objection.</p> <p>14 A. Because in science, it's better to</p> <p>15 go to the original study, first of all. When 10:33 AM</p> <p>16 you cite a study, you want to go to the</p> <p>17 original study. And the Peto actually had</p> <p>18 several publications. And the other Peto</p> <p>19 study I cited showed that the</p> <p>20 observed-to-expected ratio, one part per 10:34 AM</p> <p>21 million cause cancer.</p> <p>22 So what's important in science is</p> <p>23 to go to the original papers. There are --</p> <p>24 as I said, I reviewed over hundreds of</p> <p>25 publications. I cited over 500. Many were 10:34 AM</p>	<p style="text-align: right;">Page 413</p> <p>1 what this states?</p> <p>2 A. Yes.</p> <p>3 Q. And when it's plotted on this</p> <p>4 graphic, Doctor, do you see that a -- there</p> <p>5 is a level below which -- let me start that 10:35 AM</p> <p>6 again.</p> <p>7 When you look at the level of --</p> <p>8 in that first half of that table, it's</p> <p>9 horizontal, right; it's what would be</p> <p>10 described as a threshold? Do we agree with 10:35 AM</p> <p>11 that?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And that is using the Peto</p> <p>14 data, and it demonstrates that the incidence</p> <p>15 of liver tumors does not begin to increase 10:36 AM</p> <p>16 until the logarithmic dose at</p> <p>17 approximately -- let me start that question</p> <p>18 again.</p> <p>19 It demonstrates that there's not</p> <p>20 an increase in liver doses until we get to 10:36 AM</p> <p>21 the log 10 dose of around negative 1.5 on</p> <p>22 this.</p> <p>23 Do you see that?</p> <p>24 MR. NIGH: Form objection.</p> <p>25 BY MR. FOWLER: 10:36 AM</p>
<p style="text-align: right;">Page 412</p> <p>1 peer reviewed. And ideally the best -- and</p> <p>2 this is what all the scientists do, is you go</p> <p>3 to the original paper that has the original</p> <p>4 data.</p> <p>5 Q. Doctor, the original data from 10:34 AM</p> <p>6 Peto was used in the Zeilmaker study. That's</p> <p>7 what Dr. Zeilmaker said, right?</p> <p>8 MR. NIGH: Form objection.</p> <p>9 BY MR. FOWLER:</p> <p>10 Q. I thought we established that. 10:34 AM</p> <p>11 A. Correct.</p> <p>12 Q. Okay. And you have no problem</p> <p>13 with using the Peto data in other studies, do</p> <p>14 you?</p> <p>15 A. Correct. I went back -- it's one 10:34 AM</p> <p>16 of the important studies that --</p> <p>17 Q. Yes, sir.</p> <p>18 A. -- determines the -- that's</p> <p>19 consistent with the genotoxic carcinogen that</p> <p>20 causes cancer at low doses. 10:35 AM</p> <p>21 Q. Okay. On page 327, Doctor, let's</p> <p>22 look at this graphic using the Peto data, and</p> <p>23 let's walk through it.</p> <p>24 This graphic combines male and</p> <p>25 female from the Peto data, correct, that's 10:35 AM</p>	<p style="text-align: right;">Page 414</p> <p>1 Q. It's a terrible question.</p> <p>2 Do you see, Doctor, that the</p> <p>3 incidence of liver tumors remains the same as</p> <p>4 doses increase until a certain point and then</p> <p>5 the liver incidence -- liver tumor incidence 10:36 AM</p> <p>6 goes up, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And this is using the Peto data?</p> <p>9 A. Correct.</p> <p>10 Q. And this is demonstrates this the 10:36 AM</p> <p>11 changes or increases in doses up to a certain</p> <p>12 point did not increase the incidence of liver</p> <p>13 tumors. Isn't that what this graph shows?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. What's important in the Peto 10:37 AM</p> <p>16 study --</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. I'm just interested in does that</p> <p>19 graph --</p> <p>20 MR. NIGH: He can answer. 10:37 AM</p> <p>21 A. No, this is an interpretation --</p> <p>22 we have to go back to the original data.</p> <p>23 What Peto showed, in 4,000 rats,</p> <p>24 is as you increase the dose, the incidence of</p> <p>25 tumor induction increases. 10:37 AM</p>

<p style="text-align: right;">Page 415</p> <p>1 What's important in the Peto 2 study, is that NDMA cause cancer and NDEA 3 cause cancer. And what's important, and I 4 cited over a hundred publications from 5 multiple laboratories throughout the world, 10:37 AM 6 that NDMA and NDEA cause cancer in these 7 animal models. That's the important part. 8 And that then it's a presumed human 9 carcinogen unless proven otherwise. 10 So the important part -- modeling 10:38 AM 11 with linear versus sigmoidal extrapolation, 12 we can do mathematical modeling, but we have 13 to go back to the original data, which is in 14 Peto, in 4,000 rats, that the NDMA and NDEA 15 cause cancer at increasing doses over 16 10:38 AM 16 different doses with 60 rats per animals. 17 Q. Doctor, in the Peto study, what 18 caused the cancer in the rats that weren't 19 treated with NDMA that had 10 liver tumors? 20 What caused those tumor? 10:38 AM 21 A. That's where we go to the -- in 22 the 16 doses that they do, we go to -- at one 23 part per million, there is 25 percent 24 increase over the -- from the treated to the 25 control, and that's a very -- that is a 10:38 AM</p>	<p style="text-align: right;">Page 417</p> <p>1 experiments, in 1970, Cudolli et al., had a 2 very important study where they did frogs, 3 and they showed in the control group no frogs 4 got cancer; and then when they exposed the 5 frogs to NDMA at 5 part per million and 50 10:40 AM 6 part per million, within 9 to 11 weeks only 7 the treated animals got cancer. And within 8 16 to 18 weeks, the latency period was within 9 four to five months, 50 percent of the frogs 10 got cancer and zero control animals got 10:40 AM 11 cancer. 12 So while in Peto, at a very, very 13 small dose, some of the controls get cancer, 14 we call that spontaneous cancers, I cited 15 multiple publications in my report where, in 10:40 AM 16 a control group, there was no cancer, and 17 NDMA or NDEA stimulated cancer in -- only in 18 the treated group. That's part of animal 19 modeling, is that in certain animal models a 20 control group can get what we call 10:41 AM 21 spontaneous cancer. 22 What's important in the Peto 23 study, in the 4,000 rats, is not to focus on 24 the first few where -- and they call it the 25 observed-to-expected ratio, the first few 10:41 AM</p>
<p style="text-align: right;">Page 416</p> <p>1 potent carcinogen that causes cancer at a 2 very low dose in the animals. 3 And what's important in this case, 4 is that the FDA has allowed 96 nanogram per 5 day, which actually correlates with one in a 10:39 AM 6 thousand -- one in a hundred thousand risks 7 of getting the cancer, and that is not 8 inconsistent with a genotoxic carcinogen and 9 a dose threshold. 10 So what we know, and we rely on 10:39 AM 11 the whole field, is that these the genotoxic 12 carcinogens are very dangerous, can cause 13 cancer. And the important part of the 14 original study of Peto, is that over 16 15 different doses, that the NDMA and NDEA cause 10:39 AM 16 cancer. 17 Q. Doctor, my question to you -- I 18 think I remembered it. My question to you 19 is, what caused the cancer in the control 20 groups? When 10 tumors were observed, what 10:39 AM 21 caused their cancer? 22 A. So in certain cancer types, a 23 control group can get cancer. We call that a 24 spontaneous cancer, and that's why I don't 25 rely only on the Peto group. In other 10:40 AM</p>	<p style="text-align: right;">Page 418</p> <p>1 rats at the very, very tiny doses where there 2 was no difference, that's where you have to 3 go to higher doses, and that's where, in the 4 16 different doses, that the NDMA and NDEA 5 caused the cancer. 10:41 AM 6 But what's important here is I 7 don't rely only on Peto. I rely on hundreds 8 of publications that I cited in this paper. 9 On liver alone, I cited 32 publications that 10 NDMA and NDEA caused cancer and in many -- I 10:41 AM 11 just told you just one -- I could go into 12 other ones, but I just cited one, where only 13 the treated group caused cancer and the 14 controlled group didn't get any cancer. 15 Q. Doctor, you're not going to tell 10:42 AM 16 this jury that they should accept information 17 from a frog study where they're swimming 18 around in water treated with NDMA and accept 19 that what happens to the frog is in any way 20 comparable to the level of NDMA in orally 10:42 AM 21 ingested valsartan tablets, are you? 22 MR. NIGH: Form objection. 23 A. So we have over 60 years of 24 evidence showing the reason why every drug 25 that's ever tested in people has to go 10:42 AM</p>

<p style="text-align: right;">Page 419</p> <p>1 through animals, by the FDA, is there a 2 biological chemical, genetic similarities 3 between animals and humans. 4 So we don't rely only on one 5 species or one animal, we'll do -- every drug 10:42 AM 6 that goes into people gets tested at some 7 point in a large animal species. It could be 8 a dog, monkey, pig. And what's important in 9 that case, that those animals, the 10 bioavailability of NDMA and NDEA are much 10:43 AM 11 higher. 12 But what's important here is I -- 13 not only did I -- NDMA and NDEA cause, like I 14 said before, cancer in 10 to 18 different 15 species. I cited one study, a frog, I 10:43 AM 16 could -- and in my report I've cited hundreds 17 of papers with multiple species. I cited 18 papers where NDMA and NDEA can cause cancer 19 in snakes, in monkeys, in pigs, in swine, in 20 chickens, in cats. 10:43 AM 21 So because it's a human 22 carcinogen, we cannot do experiments on 23 people; and that's why, as I mentioned 24 before, that we do other mechanistic studies 25 with humans and then we do -- I have the epi 10:43 AM</p>	<p style="text-align: right;">Page 421</p> <p>1 MR. NIGH: Form objection. 2 A. Correct. 3 BY MR. FOWLER: 4 Q. And that demonstrates a threshold 5 both -- that demonstrates a threshold dose 10:45 AM 6 response, correct? 7 A. Correct. However -- 8 Q. Thank you. 9 A. -- what I would say is that 10 because NDMA and NDEA are genotoxic 10:45 AM 11 carcinogens, we know that these genotoxic 12 carcinogens do not have a dose threshold, 13 because of the mechanism of action that I've 14 said before. 15 MR. FOWLER: I can't read -- this 10:45 AM 16 says we know that these genotoxic 17 counter terrorists. What was his 18 statement, please? 19 A. That genotoxic carcinogens do not 20 exhibit a dose threshold. 10:45 AM 21 BY MR. FOWLER: 22 Q. I thought what's what you said, 23 sir. 24 But according to the Zeilmaker 25 article, using the Peto data on page 327, it 10:46 AM</p>
<p style="text-align: right;">Page 420</p> <p>1 studies in the report. 2 Q. Doctor, directing your attention 3 to page 328 on this exhibit. Do you see the 4 chart, Figure 6? 5 Are you with me, Doctor? 10:44 AM 6 A. Yes. 7 Q. It is called "Dose-response 8 relationship between a single administration 9 of NDMA (milligram per kilogram body weight) 10 and the induction of mesen-" -- 10:44 AM 11 A. Mesenchymal. 12 Q. -- "mesenchymal kidney tumors" -- 13 thank you -- "in the rat, 28 to 24 months 14 after administration." 15 Do you see, Doctor, a threshold 10:44 AM 16 level at the low single doses up until just 17 after 10 on this chart? 18 A. Like I -- no. 19 What was the question? 20 Q. You don't see a threshold here? 10:44 AM 21 A. Oh, yes. 22 Q. And this is up to 10 milligrams 23 per kilogram there was no increase in the 24 incidence of the kidney tumors, according to 25 this paper, correct, Doctor? 10:45 AM</p>	<p style="text-align: right;">Page 422</p> <p>1 demonstrates -- contrary to your opinion, the 2 Peto data demonstrates that there is a 3 threshold, correct? 4 MR. NIGH: Form objection. 5 A. Correct. 10:46 AM 6 BY MR. FOWLER: 7 Q. Thank you. 8 A. But as I said before -- 9 Q. There's not a at question pending. 10 A. -- I rely on hundreds of 10:46 AM 11 publications in the field; and here, in the 12 context of this case, does exogenous 13 NDMA/NDEA cause cancer, as I said before, the 14 four lines of evidence show that NDMA and 15 NDEA cause cancer in animals, similar 10:46 AM 16 mechanism in humans, and increase the risk of 17 cancer in the epi studies. 18 MR. FOWLER: 24, please. 19 (Exhibit 24, Concepts of threshold in 20 mutagenesis and carcinogenesis, marked for 10:47 AM 21 identification.) 22 BY MR. FOWLER: 23 Q. Doctor, this is an article that 24 you -- let me start that again for the 25 record. 10:48 AM</p>

<p style="text-align: right;">Page 423</p> <p>1 This article is by</p> <p>2 Dr. Kirsch-Volders, it's entitled "Concepts</p> <p>3 of threshold in mutagenesis and carcinogens,"</p> <p>4 and it's from Mutation Research in 2000.</p> <p>5 Is that a peer-reviewed journal, 10:48 AM</p> <p>6 Doctor?</p> <p>7 A. I believe so, yes.</p> <p>8 Q. And in the abstract, it starts</p> <p>9 out, "Although the existence of a threshold</p> <p>10 in the dose effect relationship is well 10:48 AM</p> <p>11 documented for many, if not most, types of</p> <p>12 toxicological effects, the existence of a</p> <p>13 threshold for the mutagenic effects of</p> <p>14 ionizing radiation and certain chemicals has</p> <p>15 been questioned since the middle of the 10:48 AM</p> <p>16 centry and only recently the questions for</p> <p>17 thresholds of radiation and chemical</p> <p>18 carcinogenesis has been addressed."</p> <p>19 Do you agree with that statement,</p> <p>20 Doctor? 10:48 AM</p> <p>21 A. Yes.</p> <p>22 Q. And if I direct your attention,</p> <p>23 please, to page 9 of this article, the</p> <p>24 conclusions.</p> <p>25 "The existence of biologically 10:49 AM</p>	<p style="text-align: right;">Page 425</p> <p>1 A. Yes. But what's important is not</p> <p>2 all mutagens can cause cancer. So mutagenic</p> <p>3 alone doesn't necessarily mean you get</p> <p>4 cancer. So that's why the readout -- and</p> <p>5 also, this paper that we're talking about, 10:50 AM</p> <p>6 Volders, is a concept paper. This is not --</p> <p>7 there's no original data. This is a concept</p> <p>8 paper that's based on this one hit -- single</p> <p>9 hit, thinking of cancer from 20 years ago.</p> <p>10 It's very outdated. That's why I mentioned 10:51 AM</p> <p>11 yesterday that IARC relies on the 10 key</p> <p>12 characteristics.</p> <p>13 We know today that cancer has</p> <p>14 evolved from only -- not just</p> <p>15 genotoxic/nongenotoxic carcinogens but cancer 10:51 AM</p> <p>16 as a whole tissue. And that's</p> <p>17 how extensive -- we talked about 10 key</p> <p>18 characteristics. So this is -- the concept</p> <p>19 of mutagenic and carcinogenic is not the same</p> <p>20 thing. Mutagenesis and carcinogenesis are 10:51 AM</p> <p>21 not the same thing.</p> <p>22 I was asked does NDMA or NDEA</p> <p>23 cause cancer not are they mutagenic.</p> <p>24 Q. Right.</p> <p>25 A. So just a different -- 10:51 AM</p>
<p style="text-align: right;">Page 424</p> <p>1 meaningful threshold dose-response curves for</p> <p>2 mutagenic and carcinogenic events is</p> <p>3 probable."</p> <p>4 Do you see that sir?</p> <p>5 A. Yes. 10:49 AM</p> <p>6 Q. "However, it is not expected in</p> <p>7 the case where the interaction between</p> <p>8 mutagen/carcinogen and the target is governed</p> <p>9 by a single direct biological reaction."</p> <p>10 Have I read that correctly? 10:49 AM</p> <p>11 A. Correct.</p> <p>12 Q. "Therefore, if a statistical</p> <p>13 threshold is observed, no important</p> <p>14 conclusions about the real threshold can be</p> <p>15 drawn before the mutagenic/carcinogenic 10:50 AM</p> <p>16 mechanism is understood."</p> <p>17 It says, the last sentence, "This</p> <p>18 would not lead to a threshold on the basis on</p> <p>19 interaction with DNA but to a threshold on</p> <p>20 the basis of adverse effect." 10:50 AM</p> <p>21 Doctor, do you understand that to</p> <p>22 mean that when DNA mutations are involved,</p> <p>23 the important threshold to consider is the</p> <p>24 effect, such as the incidence of liver</p> <p>25 tumors? 10:50 AM</p>	<p style="text-align: right;">Page 426</p> <p>1 Q. Yes, Doctor.</p> <p>2 And according to your definition</p> <p>3 of a concept paper being where there's no</p> <p>4 original data, your entire report is a</p> <p>5 concept paper under that definition, isn't 10:51 AM</p> <p>6 it, sir?</p> <p>7 MR. NIGH: Form objection.</p> <p>8 A. No. I cited many publications</p> <p>9 that cite the original papers and --</p> <p>10 BY MR. FOWLER: 10:52 AM</p> <p>11 Q. Doctor, you have no original data</p> <p>12 in your entire report. It is a concept</p> <p>13 paper.</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. So my report relies on four -- 10:52 AM</p> <p>16 like I mentioned before, four manners of</p> <p>17 evidence. So the animals, carcinogenesis and</p> <p>18 human and the epidemiology data.</p> <p>19 THE REPORTER: I'm sorry, I lost</p> <p>20 you on that. 10:52 AM</p> <p>21 "So the animals, carcinogenesis</p> <p>22 and the epi data.</p> <p>23 That's in the context of a</p> <p>24 chemical causing cancer and this context</p> <p>25 is different. Mutagenesis, as I've 10:52 AM</p>

<p style="text-align: right;">Page 427</p> <p>1 mentioned, the field has evolved over 2 the last 20 years, that not all mutagens 3 are carcinogenic, so it's a different 4 question. 5 MR. FOWLER: 25, please. 10:53 AM 6 (Exhibit 25, Dose-Response Studies and 7 'No-Effect-Levels' of N-Nitroso Compounds, 8 marked for identification.) 9 BY MR. FOWLER: 10 Q. Before you, Doctor, Exhibit 25 is 10:53 AM 11 an article by Dr. Preussmann, and this is an 12 article that you cited in Footnote 80 of your 13 report. So I trust you're familiar with it? 14 A. Yes. 15 Q. And looking at the abstract, sir, 10:54 AM 16 it states, "One major problem in the 17 evaluation of potential carcinogenic food 18 additives and contaminants is that of 19 thresholds or, better, of 20 'no-adverse-effect-levels.'" 10:54 AM 21 Do you see that, sir? 22 A. Yes. 23 Q. "Arguments in favor of the 24 postulated 'irreversibility' of carcinogenic 25 effects are based on dose-response studies, 10:54 AM</p>	<p style="text-align: right;">Page 429</p> <p>1 Do you agree with that statement, 2 sir? 3 A. Yes. 4 Q. And by "acceptable intake" at FDA, 5 if new safety data is provided, such as a 10:55 AM 6 BMDL calculation, would you agree, then, that 7 FDA should reconsider the 96 nanogram AI if 8 new facts in regard to the safety evaluation 9 are available? 10 MR. NIGH: Form objection. 10:56 AM 11 A. Correct. However, what science 12 moves is in peer-reviewed journals. Like I 13 mentioned before, IARC is very careful -- the 14 leading national -- international agency in 15 cancer causation is very careful to use 10:56 AM 16 peer-reviewed original papers in their 17 assessment on does a chemical cause cancer. 18 So the regulatory agencies that I 19 have reviewed their documents, I have not 20 seen any of them that use the -- anything 10:56 AM 21 else accept the TD 50, based on the linear 22 approach, as we've talked about. 23 And I said, the recommendations 24 from these agencies, which I agree with, is 25 that the amount of NDMA or NDEA should be 10:57 AM</p>
<p style="text-align: right;">Page 428</p> <p>1 single dose and multi generation experiments, 2 as well as on the concept of somatic mutation 3 as the first step in carcinogenesis with 4 subsequent transmittance of induced effects 5 during cell replication. The problem of 10:54 AM 6 extrapolation of results of animal 7 experiments using high doses to low exposure 8 and low incidence in man is not yet solved 9 satisfactorily." 10 Do you agree with that statement, 10:55 AM 11 Doctor? 12 A. So that sentence -- I don't 13 completely agree with that sentence. We have 14 60 years of animal literature that shows 15 up -- when a chemical causes cancer in 10:55 AM 16 animals, it's a presumed human carcinogen 17 otherwise. The dose -- it's not at a certain 18 dose. The question, does the chemical cause 19 cancer? 20 Q. Okay. The last sentence in the 10:55 AM 21 abstract, it states, "Acceptable intake 22 should never be considered constants but 23 should be changeable as soon as new facts in 24 regard to the safety evaluation are 25 available." 10:55 AM</p>	<p style="text-align: right;">Page 430</p> <p>1 limited; and even though the FDA does allow 2 96 nanogram per day, as I said before, that 3 does have a risk of one in a hundred thousand 4 to get cancer. And so in this case the 5 contaminated valsartan pills had over that 10:57 AM 6 amount of NDMA or NDEA. 7 Q. Doctor, the FDA's linear back 8 extrapolation does not include any 9 determination of the level of DNA repair that 10 is present. 10:57 AM 11 Do you agree with that, sir. 12 MR. NIGH: Form objection. Asked 13 and answered many times. 14 A. As I said before, the DNA 15 repair -- correct, the DNA repair is part of 10:57 AM 16 the 10 key characteristics of cancer, and 17 there's multiple mechanisms how NDMA and NDEA 18 can cause cancer. 19 BY MR. FOWLER: 20 Q. Okay. Doctor, do you agree -- you 10:58 AM 21 can set that exhibit aside. Thank you. 22 You agree, Doctor, that it is 23 important to assess the risk of exposure to 24 potential carcinogens in a manner that most 25 closely resembles the exposure at issue, and 10:58 AM</p>

<p style="text-align: right;">Page 431</p> <p>1 in this case the exposure at issue being the 2 orally ingested valsartan tablets with low 3 levels of NDMA. 4 A. Correct. Yes. 5 Q. That's important. You want to 10:58 AM 6 consider the route of exposure most similar 7 to the route of exposure at issue, correct? 8 A. Correct. 9 Q. Because the NDMA that's found in 10 the orally ingested valsartan tablets is 10:58 AM 11 metabolized -- 12 I'm sorry. Let me start that 13 again. 14 The exposure route from an orally 15 ingested tablet requires that tablet to first 10:59 AM 16 be metabolized by the liver, correct? 17 A. What's the question? 18 Q. Inhalation studies, Doctor, tell 19 us nothing about the risk from low level of 20 NDMA in tablets that must be swallowed, for 10:59 AM 21 example? 22 A. No -- well, we know from NDMA and 23 NDEA that they cause cancer in six different 24 routes of administration: inhalation, 25 orally, IP and intraperitoneal -- 10:59 AM</p>	<p style="text-align: right;">Page 433</p> <p>1 NDMA and NDEA. 2 And why that's important, is that 3 this carcinogen can cause cancer orally 4 or by inhalation, either way, 5 systemically, and we have higher -- 11:01 AM 6 because of the Gombar studies, which 7 were done very carefully in monkeys, 8 dogs and swine, we know there's higher 9 bioavailability when we go to larger 10 species. 11:01 AM 11 BY MR. FOWLER: 12 Q. I'll get back to that point, 13 Doctor. But my question is about the mode of 14 exposure, Doctor. 15 In an inhalation study, it becomes 11:01 AM 16 systemic -- it causes systemic exposure 17 because from the lungs it goes blood, heart, 18 body, right? 19 MR. NIGH: Hold on. Form 20 objection. And object to the colloquy 11:01 AM 21 at the beginning of the question. 22 A. What's the question? 23 BY MR. FOWLER: 24 Q. In an inhalation study you get 25 systemic exposure -- 11:01 AM</p>
<p style="text-align: right;">Page 432</p> <p>1 THE REPORTER: I'm sorry, no, no. 2 "Routes of administration, inhalation"? 3 THE WITNESS: Inhalation, oral, 4 intraperitoneal, subcutaneous, 5 intratracheal -- whether it's oral or 11:00 AM 6 inhalation, NDMA or NDEA can cause 7 cancer. 8 What's important, is that even in 9 animal studies that were -- inhaled 10 NDMA, they got cancer in systemic 11:00 AM 11 places, such as the kidney. So we all 12 already know -- and what we know is that 13 when we convert the bioavailability from 14 rodents to humans, what we know -- and 15 these were studies done by Gombar, 11:00 AM 16 there's three studies I cited in the 17 monkey, 49 percent bioavailability; in 18 the swine, 67 percent bioavailability; 19 and in the dog, 93 percent. In the 20 rodent it's 8 percent bioavailable. 11:00 AM 21 So when we talk about translating 22 the results that I just said, inhalation 23 in animals can lead to systemic 24 exposure. When we go to a human, you 25 have increased bioavailability of the 11:00 AM</p>	<p style="text-align: right;">Page 434</p> <p>1 A. Yes. 2 Q. -- because it goes directly into 3 the blood from the lungs to the heart and its 4 pumped all over the body, right? 5 MR. NIGH: Hold on. You need to 11:01 AM 6 let him finish his question before you 7 answer. 8 MR. FOWLER: So he can object. 9 A. Correct. 10 MR. NIGH: And not just so I can 11:02 AM 11 object. I don't know why you filled 12 that in for me. It's so that you can 13 finish the question, he can answer, and 14 you have a clean record. That's what 15 we're supposed to do here. 11:02 AM 16 BY MR. FOWLER: 17 Q. So you agree, Doctor, that 18 inhalation studies where the NDMA goes 19 directly to the circulatory system is a 20 different mode of exposure from an orally 11:02 AM 21 ingested tablet where NDMA must be 22 metabolized by the liver, correct? 23 A. Correct. 24 Q. It is not comparable to suggests 25 that -- well, strike that. 11:02 AM</p>

<p style="text-align: right;">Page 435</p> <p>1 Doctor, massive doses given to</p> <p>2 animals by an IP, an intraperitoneal</p> <p>3 injection, are not reflective of the exposure</p> <p>4 from low level NDMA in the tablets that must</p> <p>5 be swallowed. 11:02 AM</p> <p>6 Do you degree with that also?</p> <p>7 MR. NIGH: Form objection.</p> <p>8 A. I would agree with that. But,</p> <p>9 however, I said there's six different ways</p> <p>10 that NDMA has been given to animals all cause 11:02 AM</p> <p>11 cancer.</p> <p>12 Q. Isn't the question, Doctor,</p> <p>13 whether the NDMA, in orally ingested tablets,</p> <p>14 whether that incremental increase of NDMA</p> <p>15 exogenous exposure increases the risk of 11:03 AM</p> <p>16 cancer? Isn't that the question, sir?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 A. Yes. I was asked, does orally</p> <p>19 ingested valsartan contaminated NDMA cause</p> <p>20 human cancer. To answer that question, as I 11:03 AM</p> <p>21 mentioned before, I used inhalation studies</p> <p>22 in animals and people, and I used oral --</p> <p>23 where NDMA was given orally, and both of them</p> <p>24 cause cancer or in humans increase your risk</p> <p>25 of cancer. Using the dietary occupational 11:03 AM</p>	<p style="text-align: right;">Page 437</p> <p>1 studies, Doctor, under routes of exposure</p> <p>2 here it states, "The optimal route should</p> <p>3 most closely mimic the major human exposure</p> <p>4 route where possible."</p> <p>5 Have I read that correctly, sir? 11:05 AM</p> <p>6 A. Correct.</p> <p>7 Q. Inhalation studies and rubber</p> <p>8 workers with dermal exposure are not the</p> <p>9 route of exposure that's at issue in this</p> <p>10 case, correct, sir? 11:06 AM</p> <p>11 A. Correct.</p> <p>12 Q. Okay.</p> <p>13 A. However -- so, in an ideal world,</p> <p>14 we would give NDMA and NDEA -- pure NDEA</p> <p>15 orally. However, because it's a human 11:06 AM</p> <p>16 carcinogen that's not possible. So I relied</p> <p>17 on my report not only on Hidajat inhalation</p> <p>18 studies, but I relied on multiple epi studies</p> <p>19 where -- using diet, where different types of</p> <p>20 cancer had an increase risk of cancer with 11:06 AM</p> <p>21 the amount of NDMA in the diet and that diet</p> <p>22 was oral.</p> <p>23 So I not only relied on inhalation</p> <p>24 with Hidajat, which is a very important study</p> <p>25 because there's 36,000 people over a 49-year 11:06 AM</p>
<p style="text-align: right;">Page 436</p> <p>1 studies, such as Hidajat, which is a very</p> <p>2 important study where the NDMA was inhaled,</p> <p>3 and that caused 10 type -- that increased the</p> <p>4 risk of 10 different types of cancer related</p> <p>5 to the cumulative exposure of NDMA. 11:03 AM</p> <p>6 MR. FOWLER: 26, please.</p> <p>7 (Exhibit 26, Scientific Concepts, Value, and</p> <p>8 Significance of Chemical Carcinogenesis</p> <p>9 studies, marked for identification.)</p> <p>10 Q. Before you, Doctor, is a study by 11:04 AM</p> <p>11 James Huff, "Scientific concepts, value, and</p> <p>12 significance of chemical carcinogenesis</p> <p>13 studies," from 1991, correct?</p> <p>14 A. Yes.</p> <p>15 Q. Is the annual review pharmacology 11:04 AM</p> <p>16 toxicology [sic] a peer-reviewed journal?</p> <p>17 A. I would believe so, yes.</p> <p>18 Q. And you rely on this in your</p> <p>19 report, it's from Footnote 40, sir, correct?</p> <p>20 A. Correct. 11:05 AM</p> <p>21 Q. And directing your attention in</p> <p>22 this page, sir, to 629, it's the page number</p> <p>23 on the top right.</p> <p>24 Referring to the value and</p> <p>25 significance of chemical carcinogenesis 11:05 AM</p>	<p style="text-align: right;">Page 438</p> <p>1 follow up; and, like I said before, 10</p> <p>2 different types of cancer were increased. So</p> <p>3 what we do in science is we have to use a</p> <p>4 whole set of papers, not rely on only one</p> <p>5 paper. 11:07 AM</p> <p>6 Q. Got it, Doctor.</p> <p>7 In this case, in order for -- let</p> <p>8 me start that again.</p> <p>9 In this case, the NDMA detected in</p> <p>10 the valsartan tablets would go to the liver 11:07 AM</p> <p>11 first, correct?</p> <p>12 A. So --</p> <p>13 Q. Let me start the question again.</p> <p>14 In this study, Doctor -- in this</p> <p>15 litigation, Doctor, the exposure to the 11:07 AM</p> <p>16 levels of NDMA detected in the valsartan</p> <p>17 tablets because of oral ingestion, would</p> <p>18 first go -- first be metabolized by the</p> <p>19 liver, correct?</p> <p>20 MR. NIGH: Form objection. 11:07 AM</p> <p>21 A. Correct. There's a first-pass</p> <p>22 metabolism initially.</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. That's right, Doctor.</p> <p>25 And the liver has the highest 11:08 AM</p>

<p style="text-align: right;">Page 439</p> <p>1 level of the cytochrome P450 2E1 enzymes, 2 correct, Doctor. 3 A. Correct. They're highly expressed 4 in the liver, the enzymes. 5 Q. And, Doctor, NDMA, you would 11:08 AM 6 agree, is subject to first-pass metabolism in 7 the liver, right? 8 A. Correct. 9 Q. And in order to escape the liver, 10 the liver would have to be saturated to the 11:08 AM 11 point where first-pass metabolism would not 12 be successful in eliminating the NDMA. 13 Do we agree with that. 14 MR. NIGH: Form objection. 15 A. So I'm not -- what's important 11:08 AM 16 here, like I said before, that the 17 bioavailability in humans for NDMA is much 18 higher than in rodents. So in rodents it's 19 easier -- at certain doses you have to go 20 higher to scope the first-pass metabolism, 11:09 AM 21 but because of the studies we know from 22 Gombard, with the higher bioavailability in 23 swine, monkey and dogs, which is much higher, 24 like I said, in rodents at 8 percent, in the 25 larger animals, 49 to 93 percent, we know in 11:09 AM</p>	<p style="text-align: right;">Page 441</p> <p>1 NDMA is excreted without going through the 2 rest of the body, correct? 3 MR. NIGH: Form objection. 4 A. Correct. If it's only first-pass 5 metabolism -- if a drug only goes through 11:10 AM 6 first metabolism, it won't make it to the 7 systemic. But what I'm saying is that we 8 know from the epi data that orally ingested 9 NDMA through the diet increased the risk of 10 multiple systemic cancers, and I've 11:10 AM 11 documented it in my report. It wasn't only 12 liver cancer. There's other cases where the 13 lung, the gastric -- yeah, in other systemic 14 cancers there's an increased risk. Even, for 15 example, esophageal and other types. 11:11 AM 16 BY MR. FOWLER: 17 Q. Doctor, there is a level of NDMA 18 that would be successfully metabolized with 19 first-pass metabolism; isn't that correct? 20 A. Correct. 11:11 AM 21 Q. That's what first-pass metabolism 22 means, right? 23 A. Correct. 24 Q. Tell the jury what what first-pass 25 metabolism means, sir. 11:11 AM</p>
<p style="text-align: right;">Page 440</p> <p>1 humans likely have a higher bioavailability. 2 What that means is that the NDMA 3 can go past the first-pass metabolism in the 4 liver. And, in fact, we know that from the 5 occupational -- from the dietary studies, 11:09 AM 6 that there's an increased risk of people who 7 had NDMA in their diet who took -- who had 8 NDMA exposed orally, had increased risk of 9 cancer. 10 So we know in the gastric studies 11:09 AM 11 I've documented in my report, with Song and 12 four other studies, there's statistical 13 increase, and in my report I detailed the 14 other types where the dietary studies, in 15 which the NDMA exposure is orally, have an 11:10 AM 16 increased risk of cancer. 17 BY MR. FOWLER: 18 Q. Doctor, in order for NDMA to 19 escape the liver, it would have to not be 20 successfully metabolized through first-pass 11:10 AM 21 metabolism, correct? 22 Strike that. Ask it a different 23 way. 24 When NDMA is successfully 25 metabolized with first-pass metabolism, that 11:10 AM</p>	<p style="text-align: right;">Page 442</p> <p>1 A. Right, that's when -- 2 Q. Explain first-pass metabolism. 3 A. When a drug is taken orally, it is 4 metabolized through GI tract and the liver, 5 through the small intestine, liver, and if a 11:11 AM 6 drug is completely metabolized by first-pass 7 metabolism, it will not make it past the 8 liver. 9 Q. Okay. And there is a level above 10 which the liver's first-pass metabolism is 11:12 AM 11 not successful, for whatever drug or chemical 12 we're talking about, right? 13 MR. NIGH: Form objection. 14 Q. Let me ask a better question. 15 We know for example that the 11:12 AM 16 active pharmaceutical ingredient in valsartan 17 would not be effective in treating 18 hypertension if it was metabolized by the 19 liver and left the body, right; so we know 20 that the actual active ingredient that 11:12 AM 21 successfully treats hypertension leaves the 22 liver, right? 23 MR. NIGH: Form objection. 24 A. Right. So valsartan is the ARB 25 inhibitor, it blocks angiotensin -- 11:12 AM</p>

<p style="text-align: right;">Page 443</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. Right.</p> <p>3 A. -- angiotensin II, it's an</p> <p>4 angiotensin receptor blocker, and those</p> <p>5 receptors are expressed systemically. 11:13 AM</p> <p>6 Q. And when the valsartan tablet is</p> <p>7 taken, it goes stomach, small intestine, and</p> <p>8 it's through -- is it ileum that has the</p> <p>9 mesentery artery that goes to the liver,</p> <p>10 correct, or the duod- -- 11:13 AM</p> <p>11 A. Correct.</p> <p>12 Q. Right. And that's how the</p> <p>13 valsartan tablet gets to the liver, right?</p> <p>14 A. Correct, the first pass.</p> <p>15 Q. It's not -- when it's in the 11:13 AM</p> <p>16 stomach, the valsartan tablet is not</p> <p>17 metabolized such that NDMA is exposed; isn't</p> <p>18 that correct?</p> <p>19 MR. NIGH: Objection.</p> <p>20 A. I don't know what the question 11:13 AM</p> <p>21 here is.</p> <p>22 BY MR. FOWLER:</p> <p>23 Q. The question is, just swallowing</p> <p>24 the valsartan tablet does not expose the</p> <p>25 stomach to NDMA, does it? 11:13 AM</p>	<p style="text-align: right;">Page 445</p> <p>1 throughout the body, and that's -- and that,</p> <p>2 in conjunction with the Anderson 1991 paper,</p> <p>3 where they gave NDMA to monkeys and showed in</p> <p>4 32 different tissues that these adducts were</p> <p>5 expressed; that that was because these 11:15 AM</p> <p>6 cytochrome P450s are expressed throughout the</p> <p>7 body; while liver is the highest expression,</p> <p>8 they're expressed everywhere.</p> <p>9 Q. Doctor, in order for the NDMA to</p> <p>10 get to any other system in the body, it would 11:15 AM</p> <p>11 have to escape the liver.</p> <p>12 Can we agree on that?</p> <p>13 MR. NIGH: Form objection.</p> <p>14 A. Correct. To go -- systemically.</p> <p>15 BY MR. FOWLER: 11:15 AM</p> <p>16 Q. It would have to escape the liver</p> <p>17 in order to reach any of those other organs</p> <p>18 that you're talking about; correct?</p> <p>19 A. Yes.</p> <p>20 Q. And NDMA itself is fairly stable 11:15 AM</p> <p>21 without being metabolized, correct?</p> <p>22 MR. NIGH: Form objection.</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. Withdrawn.</p> <p>25 Doctor, you have no data in your 11:15 AM</p>
<p style="text-align: right;">Page 444</p> <p>1 MR. NIGH: Form objection.</p> <p>2 A. The NDMA will go through the</p> <p>3 stomach.</p> <p>4 BY MR. FOWLER:</p> <p>5 Q. The tablet will go through the 11:13 AM</p> <p>6 stomach?</p> <p>7 A. Yeah.</p> <p>8 Q. It's not broken down until it gets</p> <p>9 past the stomach, right?</p> <p>10 MR. NIGH: Form objection. 11:13 AM</p> <p>11 A. So NDMA -- the enzymes that</p> <p>12 metabolize NDMA, the cytochrome P450s, are</p> <p>13 highly expressed throughout the body. As I</p> <p>14 mentioned in the report, the 10 tumor types</p> <p>15 that I showed through my report that NDMA and 11:14 AM</p> <p>16 NDEA can cause in humans, cytochrome P450s</p> <p>17 are expressed by each of those 10 organs and</p> <p>18 tissues.</p> <p>19 So, for example, gastric expresses</p> <p>20 cytochrome P450s, bladders expresses 11:14 AM</p> <p>21 cytochrome P450s, kidney expresses the</p> <p>22 cytochrome P450s. And that's actually a very</p> <p>23 important point. Why NDMA and NDEA are very</p> <p>24 dangerous is that the enzymes that quickly</p> <p>25 metabolize them into ion are expressed 11:14 AM</p>	<p style="text-align: right;">Page 446</p> <p>1 report where you -- and you have no opinion</p> <p>2 in your report as to what level of NDMA is</p> <p>3 necessary to escape the liver, do you?</p> <p>4 A. I'm not sure of the question. I</p> <p>5 don't go into endogenous levels of NDMA 11:16 AM</p> <p>6 because it's not -- there's no scientific</p> <p>7 reliable study to measure the levels --</p> <p>8 Q. We're not talking about that, sir.</p> <p>9 We've established that there is a</p> <p>10 level of NDMA that is successfully first 11:16 AM</p> <p>11 metabolized -- first-pass metabolized by the</p> <p>12 liver, correct?</p> <p>13 A. Correct.</p> <p>14 Q. And you have not done any -- you</p> <p>15 have not reached any opinion as to what level 11:16 AM</p> <p>16 of NDMA is necessary to not be successfully</p> <p>17 metabolized with first-pass metabolism, have</p> <p>18 you?</p> <p>19 MR. NIGH: Form objection.</p> <p>20 A. So, in my report, in the 11:17 AM</p> <p>21 bioavailability section, which, as I just</p> <p>22 said before, what's important in rodents,</p> <p>23 there's 8 percent bio --</p> <p>24 MR. NIGH: Hold on. Hold on.</p> <p>25 You have to stop shaking your head 11:17 AM</p>

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<p style="text-align: right;">Page 447</p> <p>1 at every answer. That is completely 2 inappropriate. You're pursing your lip; 3 you're shaking your head, not on video, 4 but I'm seeing it time and time again. 5 He's answering the question. 11:17 AM 6 Maybe it's not the answer that you want 7 because it's not your theory, but he's 8 answering. 9 MR. FOWLER: You can believe that 10 he's answering, Counsel -- 11:17 AM 11 MR. NIGH Absolutely, he's 12 answering. 13 MR. FOWLER: -- but the record 14 will speak for itself. 15 THE WITNESS: So, as I was saying, 11:17 AM 16 when we go to humans, the reason I 17 only -- the first-pass metabolism is 18 very -- it's very important to rodents, 19 if you're a mouse or rat, because 20 there's only 8 percent bioavailability. 11:17 AM 21 But as you get into a larger species, 22 like human, the systemic -- throughout 23 my report I talk about systemic cancer 24 caused by NDMA and NDEA, but because 25 it's a human carcinogen and we can't 11:18 AM</p>	<p style="text-align: right;">Page 449</p> <p>1 MR. FOWLER: Let's mark 27, 2 please. 3 (Exhibit 27, Interspecies Scaling of the 4 Pharmacokinetics of N-Nitrosodimethylamine, 5 marked for identification.) 11:19 AM 6 BY MR. FOWLER: 7 Q. Are you familiar with this study, 8 Doctor? 9 A. Yes. 10 Q. And you elected to cite in your 11:19 AM 11 report the first two Gombar studies, but you 12 omitted this study from your references, 13 Doctor; isn't that correct? 14 A. I believe I reference three Gomar 15 papers. 11:20 AM 16 Q. You have all three. Then I must 17 be mistaken. 18 A. I can check. 19 Yeah, I reference -- 213 is 20 actually this paper, and the reference 214 is 11:20 AM 21 the Gombar and swine reference, and 215 is 22 the Beagle Gombar. 23 Q. Okay Perfect. Thank you, sir. I 24 apologize. I missed that in your paper. 25 So you do rely on this in your 11:20 AM</p>
<p style="text-align: right;">Page 448</p> <p>1 study carefully the amount of first-pass 2 metabolism in a human, because it would 3 be unethical to do that, to subject 4 someone to a carcinogen. 5 What Gombar and other people in 11:18 AM 6 the field have studied that -- they've 7 asked that question, what is the 8 bioavailability systemically in a large 9 animal, which I mention in my report, 10 that large animals are very similar to 11:18 AM 11 humans, the genetic, the metabolic, the 12 biochemical properties of large animals 13 are used throughout the world, and the 14 FDA requires it to get into -- a drug 15 into people. 11:18 AM 16 And, as I mentioned before, the 17 monkey, 49 percent bioavailability; the 18 swine, 67 percent; a dog, 93 percent; so 19 that tells us that in a human, likely 20 the NDMA is going systemically, because 11:18 AM 21 a human is closer to a larger animal 22 than a rodent. 23 BY MR. FOWLER: 24 Q. Okay. I think you want to talk 25 about Gombar. 11:19 AM</p>	<p style="text-align: right;">Page 450</p> <p>1 paper. And you rely on it for the statements 2 you've been making the last several minutes 3 about bioavailability, correct? 4 A. Correct. 5 Q. Let's look Dr. Gombar's 11:20 AM 6 discussion, which is on the second page. 7 "The role of pharmacokinetics of a 8 carcinogen plays -- 9 A. The discussion on the third page? 10 Q. Oh, yeah, I'm double-sided. 11:21 AM 11 Sorry. Yeah, third page. 12 Under "Discussion, The role that 13 the pharmacokinetics of a carcinogen plays in 14 its impact both qualitatively (i.e. target 15 organ) and quantitatively (i.e. risk 11:21 AM 16 assessment), has not been adequately 17 determined for most compounds assumed or 18 suspected to be human carcinogens." 19 Do you agree with that 20 statement? 11:21 AM 21 A. Correct. I mean, this is 30 years 22 ago, yes, yeah. 23 Q. Yes, sir. Yes, sir. 24 You rely on it -- and you rely on 25 nothing else for your bioavailability 11:21 AM</p>

30 (Pages 447 - 450)

<p style="text-align: right;">Page 451</p> <p>1 opinions in the Gombar studies; isn't that 2 correct. 3 MR. NIGH: Form objection. 4 A. Yes, I did rely on this paper. 5 BY MR. FOWLER: 11:21 AM 6 Q. Okay. And if we look -- 7 continuing in the discussion, the bottom of 8 that column it says "It is clear these 9 factors play a role, since, for carcinogens, 10 such as the nitrosamines, the route of 11:21 AM 11 administration can alter the 12 organospecificity as can manipulation of the 13 clearance with inducers or inhibitors of 14 metabolism." 15 Have I read that correctly? 11:22 AM 16 A. Correct. 17 Q. And if you look -- I guess we're 18 now on the fourth page, first column, sir, at 19 the bottom of that first paragraph, it 20 states, "The use of carcinogenesis data 11:22 AM 21 obtained in small species (rodents) to 22 estimate risk in larger species (humans), 23 which do not take these differences into 24 account, may introduce error" (as read). 25 Do you agree with that statement, 11:22 AM</p>	<p style="text-align: right;">Page 453</p> <p>1 A. In the context of this paper, yes. 2 Q. This is the paper you rely upon 3 for your bioavailability opinions? 4 A. Yeah, but then I cite in a swine, 5 a pig, and then a Beagle. So I don't only 11:23 AM 6 rely on this paper. And Bombar himself and 7 the people who review Gombar papers, the 8 bottom line is they use it and I use it to 9 mimic in a human the bioavailability of NDMA. 10 Q. Doctor, in the series of Gombar 11:24 AM 11 articles, this is the third one, and he 12 himself relies upon the Beagle and the swine 13 study in this paper. 14 Did you understand that? 15 A. Yes. 11:24 AM 16 Q. Okay. So it's actually using the 17 same data that you're talking about from 18 those prior studies in reaching conclusions 19 in this study. 20 Do we agree on that? 11:24 AM 21 A. In my report, I don't only rely on 22 the Gombar peak -- these studies. I rely on 23 an entire totality. For example, the 24 carcinogens can cause cancer systemically in 25 animals. There's an increase risk of the 11:24 AM</p>
<p style="text-align: right;">Page 452</p> <p>1 Doctor? 2 A. Yes. 3 Q. And it states on the next 4 paragraph, "We have attempted this type of 5 analysis with the well-known carcinogen NDMA. 11:22 AM 6 It is well established that NDMA must be 7 metabolized to the ultimate methylating 8 species to observe its toxic effect." 9 Do you agree with that 10 statement? 11:23 AM 11 A. Yes. 12 Q. If you look further down that 13 column, sir, the -- just above of the 14 equation it says, "In spite of good 15 correlations between body weight and both 11:23 AM 16 clearance and V" -- I can't even read that 17 subscript -- "there was not a uniformly 18 predictable relationship between body weight 19 and bioavailability? 20 MR. NIGH: It's "ss." 11:23 AM 21 MR. FOWLER: Good for you. That's 22 subscript. 23 BY MR. FOWLER: 24 Q. Do you agree with that statement, 25 Doctor? 11:23 AM</p>	<p style="text-align: right;">Page 454</p> <p>1 cancer when you're exposed to quantitative 2 amounts of NDMA in humans. 3 So when I rely on an opinion in a 4 report, I'm relying on these 500 publications 5 as a total. 11:24 AM 6 Q. Doctor, I'm talking about the 7 Gombar article that's in front of you, and my 8 question was simply, this third article in 9 his series uses the data from the Beagle and 10 the swine study; isn't that correct? 11:25 AM 11 MR. NIGH: Form objection. 12 A. Correct. 13 BY MR. FOWLER: 14 Q. Okay. So this paper is the result 15 of those bioavailability studies of swine, 11:25 AM 16 Beagle, and I believe the monkey was the 17 third one that's discussed in this paper as 18 well, correct? 19 A. Correct. 20 MR. NIGH: Form objection. 11:25 AM 21 Q. Now, Doctor, at the bottom of the 22 column, below the equation, it says "The wide 23 interspecies difference in bioavailability of 24 NDMA is difficult to explain." 25 Do you agree with that statement? 11:25 AM</p>

<p style="text-align: right;">Page 455</p> <p>1 A. Correct. Well, yeah -- what 2 Gombar did was compare a monkey to a swine to 3 a dog. So sometimes in science you don't 4 have an exact correlation, so you have to put 5 it in the context of the question that you're 11:26 AM 6 asking. And in this case we're asking the 7 question, does NDMA and NDEA cause cancer? 8 So in a very tight correlation, in 9 an ideal world, you have a very linear curve 10 between body weight and bioavailability, and 11:26 AM 11 we call it the R-value of .99 is a perfect 12 linear curve. 13 THE REPORTER: I'm sorry. We call 14 it an R-value of? 15 THE WITNESS: R-value. 11:26 AM 16 THE REPORTER: Of? 17 THE WITNESS: Of correlation 18 coefficient. 19 And, in this case, what they're 20 just saying that -- they're trying to 11:26 AM 21 come up with an explanation of there was 22 a variability. The dog had 90 -- the 23 monkey was 49 percent, the swine was 67 24 percent, and the dog was 93 percent; 25 and, actually, another study showed the 11:26 AM</p>	<p style="text-align: right;">Page 457</p> <p>1 as mouse, rats, there's an 8 percent 2 bioavailability and in larger animals there's 3 a higher bioavailability. The human is 4 closer to a swine, dog, and monkey than a 5 rodent. So that's where -- not only me but 11:28 AM 6 other people have come to that conclusion 7 that a human is more likely to be like a rat, 8 pig -- a swine or a monkey then a rodent. 9 So when it comes to 10 bioavailability, our bioavailability will be 11:28 AM 11 almost tenfold higher than the rodent. If 12 you look at 8 percent, you can calculate -- 13 in a dog there's 93 percent in one study. 14 And there's another study that I've cited 15 which had a hundred percent bioavailability. 11:28 AM 16 So these aren't experiments you 17 can do in people because it's a carcinogen. 18 So we have to rely on peer-reviewed 19 publications in animals for the -- to 20 quantify the amount of bioavailability in 11:29 AM 21 people. 22 Q. Dr. Gombar, his findings are 23 completely inconsistent with what you're 24 saying, Doctor, aren't they? 25 Well, let me start that question 11:29 AM</p>
<p style="text-align: right;">Page 456</p> <p>1 dog could be a hundred percent 2 bioavailability. 3 BY MR. FOWLER: 4 Q. Doctor, Dr. Gombar concludes that 5 the differences in the bioavailability 11:27 AM 6 between the animal species is not -- cannot 7 simply be due to the size of the animal, 8 correct, including humans? 9 MR. NIGH: Form objection. 10 A. And as I've said, in the context 11:27 AM 11 of this case, it's inappropriate to try to 12 convert the body weight of rodents to a body 13 weight of a human, because the mechanism of 14 action of this -- of NDMA and NDEA in 15 inducing these potent electrophilic 11:27 AM 16 compounds. 17 BY MR. FOWLER: 18 Q. Doctor, the result of Dr. Gombar 19 does not conclude that there's high 20 bioavailability in humans, based on the 11:27 AM 21 studies he did in Beagles, swines, and 22 monkeys, correct? 23 MR. NIGH: Form objection. 24 A. In the context of -- so when I 25 looked at the literature and in rodents such 11:28 AM</p>	<p style="text-align: right;">Page 458</p> <p>1 again. 2 Dr. Gombar's study that you have 3 before you does not agree that you can take 4 that data from mice, monkeys and swine in the 5 linear fashion to predict bioavailability in 11:29 AM 6 humans, that's his finding, that you can't do 7 what you're saying you did? 8 MR. NIGH: Form objection. 9 A. I disagree with that. In 10 science -- and not only me, like I said, 11:29 AM 11 other people will use large animals to mimic 12 humans. 13 In fact, the FDA, in order to get 14 a drug into people, you have to go through 15 some type of large animal toxicity study, 11:29 AM 16 whether it's a monkey or a dog, you cannot 17 even get into people. And the reason for 18 that is larger animals are very close 19 metabolically, genetically. In fact, I cite 20 in my report, in a Nature biotech 11:30 AM 21 publication, a key paper, a landmark paper 22 that showed monkeys have 93 percent homology 23 to humans when it comes to your DNA and your 24 gene. 25 So in an ideal world, even in our 11:30 AM</p>

<p style="text-align: right;">Page 459</p> <p>1 lab, we would study large animals. However, 2 large animals are more expensive; they're 3 more difficult to do experiments with. So 4 many labs can't do large animals. But there 5 is -- so before you can even test any drug in 11:30 AM 6 humans, let alone to try to do -- we're 7 talking about a carcinogen here. 8 Before you can do that, people go 9 to rodent species. So we know from the 10 rodent -- each paper that I cite in here 11:30 AM 11 has -- is a piece of a puzzle, and science is 12 like you're putting the puzzle together. So 13 it's not like one piece of the puzzle is more 14 important than the other. 15 So the rodent specie animal data 11:31 AM 16 is very important. It shows that NDMA causes 17 cancer. And these studies and the 18 bioavailability are important because we 19 can't do these studies in humans. And the 20 body weight -- like I said before, the body 11:31 AM 21 weight of these large animals are closer to 22 humans than the rodent. 23 Q. Doctor, my questions are strictly 24 about this article right now. Okay? 25 And directing your attention in 11:31 AM</p>	<p style="text-align: right;">Page 461</p> <p>1 worded. Not the way it was worded. 2 / 3 BY MR. FOWLER: 4 Q. Doctor -- 5 A. So if you go to the next sentence. 11:32 AM 6 "In general, the smaller species tended to 7 show lower bioavailability than the larger 8 species." 9 A human is closer to a dog, a pig, 10 and a monkey than a rodent. So when it comes 11:32 AM 11 to bioavailability, the bioavailability in 12 rodents, the next sentence is absolutely 13 supporting what I'm saying, that, "In 14 general, smaller species tend to show lower 15 bioavailability than larger" series [sic]. 11:32 AM 16 The sentence before, what I tried 17 to explain before, that in science sometimes 18 you need a certain number of data points to 19 get a tight correlation coefficient that we 20 call and that you need multiple data points 11:33 AM 21 to get a perfect correlation of .99. 22 In this case, sometimes in science 23 you have to go with the data that you have, 24 we have as a scientist. And in this case we 25 have data showing the bioavailability in 11:33 AM</p>
<p style="text-align: right;">Page 460</p> <p>1 the first column, on 4369 where we are, it 2 states that -- the paragraph starting "In 3 spite." 4 "In spite of good correlations 5 between body weight and both clearance and 11:31 AM 6 VSS, there was not a uniformly predictable 7 relationship between body weight and 8 bioavailability," Doctor, that's what Gombar 9 has found. 10 Do you disagree with that 11:32 AM 11 statement? 12 MR. NIGH: Hold on. Objection. 13 Objection to the form. Objection to the 14 colloquy of the question. The prior 15 questions have not been strictly on this 11:32 AM 16 document. I think the record will show 17 that. 18 MR. FOWLER: Please. 19 MR. NIGH: No, no. You put a 20 colloquy that said my questions are 11:32 AM 21 strictly about this article. It was 22 not. The prior question was not. 23 MR. FOWLER: It was a hundred 24 percent, Counsel. 25 MR. NIGH: Not the way it was 11:32 AM</p>	<p style="text-align: right;">Page 462</p> <p>1 three different large species is closer, that 2 that bioavailability is much higher than that 3 that was in rodents. 4 Q. Doctor, the finding is that it is 5 not uniformly predictable relationship 11:33 AM 6 between body weight and bioavailability. 7 That's what he found, correct? 8 MR. NIGH: Object to form. This 9 has been asked and answered multiple 10 times. 11:33 AM 11 A. I think the sentence that I just 12 said in the paper, "In general, smaller 13 species tend to show lower bioavailability," 14 like the rodent, 8 percent bioavailability, 15 than than the larger species. 11:33 AM 16 BY MR. FOWLER: 17 Q. And could that be because rodents 18 have a lower hepatic blood flow, Doctor? 19 Do you know what that is? 20 MR. NIGH: Form objection. 11:34 AM 21 A. Yes. 22 BY MR. FOWLER: 23 Q. Okay. And it states, "If it is 24 assumed that NDMA is cleared solely by 25 hepatic metabolism, bioavailability will 11:34 AM</p>

<p style="text-align: right;">Page 463</p> <p>1 ultimately depend on C" subscript, "int and 2 hepatic blood flow (Qh)." 3 Correct, Doctor, that's what it 4 says? 5 A. Correct, if the systemic blood 11:34 AM 6 flow is greater then the blood flow going to 7 the liver, then you have increased 8 bioavailability systemically. 9 Q. If the blood flow in the liver -- 10 the hepatic blood flow is greater, that is 11:34 AM 11 what effects bioavailability, Doctor; isn't 12 it? 13 MR. NIGH: Form objection. 14 BY MR. FOWLER: 15 Q. Withdrawn. 11:34 AM 16 Doctor, the bottom of the page, 17 "The wide interspecies difference in 18 bioavailability of NDMA is difficult to 19 explain." 20 Dr. Gombar doesn't believe, 11:34 AM 21 according to this, that you can simply look 22 at body weight and determine bioavailability. 23 That's what he's saying, correct? 24 MR. NIGH: Form objection. 25 A. Like -- I think we've said this 11:35 AM</p>	<p style="text-align: right;">Page 465</p> <p>1 rat? 2 A. Yes. 3 Q. Okay. Good. 4 THE REPORTER: Before we go to the 5 next, can we please take a break? 11:36 AM 6 MR. FOWLER: By all means. 7 THE VIDEOGRAPHER: The time is 8 11:36. We're off the record. 9 (Recess taken at 11:37 a.m. to 12:02 p.m.) 10 THE VIDEOGRAPHER: The time is 12:02 PM 11 12:01. We're back on the record. 12 BY MR. FOWLER: 13 Q. Doctor, in your report on page 14 204, you contend that NDMA can activate tumor 15 dormancy? 12:02 PM 16 ZOOM PARTICIPANT: We can't hear 17 you. Steve, you're on mute. 18 MR. FOWLER: Sorry. Start that 19 again. 20 BY MR. FOWLER: 12:02 PM 21 Q. Doctor, in your report on page 22 204, you contend that NDMA can activate tumor 23 dormancy. 24 Do you recall that section of your 25 report? 12:02 PM</p>
<p style="text-align: right;">Page 464</p> <p>1 before. So swine, 67 percent; dog, 93 to 100 2 percent; and monkey, 49 percent. 3 So there's not -- so in science, 4 like I said before, we have to come up with 5 the -- nobody can do the experiment in human 11:35 AM 6 bioavailability because it's a carcinogen. 7 So a human is more likely like a body weight 8 of a large animal than a rodent. So it is 9 likely that the bioavailability of NDMA -- 10 and I said before, I don't rely on one paper. 11:35 AM 11 In the context of these three papers, that's 12 what he's saying, the wide interspecies 13 difference in bioavailability is difficult to 14 explain. 15 But in the same paper, in general, 11:36 AM 16 the smaller species tend to show lower 17 bioavailability than the larger species. 18 Q. Isn't that because their liver 19 doesn't function the same, Doctor? 20 MR. NIGH: Form objection. 11:36 AM 21 A. There's multiple mechanisms that 22 take into account bioavailability. That's 23 one of them. 24 Q. Okay. Can we agree that human DNA 25 repair greatly capacity exceeds that of a 11:36 AM</p>	<p style="text-align: right;">Page 466</p> <p>1 A. Yes. 2 Q. And when you're referring to 3 activating tumor dormancy, you're referring 4 to a subclinical tumor that exists already in 5 the body, correct? I'm just trying to take 12:02 PM 6 this in baby steps. 7 A. Yes. Yes. 8 Q. Okay. And it's -- any tumor that 9 you would contend is -- any, quote/unquote, 10 "dormant tumor" that you would contend is 12:03 PM 11 affected by NDMA would be a cancerous tumor 12 that was not caused by the NDMA, it was 13 something that preexisted, correct? 14 MR. NIGH: Form objection. 15 A. So a dormant tumor -- I think 12:03 PM 16 we're on the same page. A dormant tumor is 17 not a cancerous tumor. It's dormant. It can 18 be proliferating, so it can be alive but it's 19 not growing. 20 Q. Okay. 12:03 PM 21 A. And it's -- and the reason -- I 22 can get into how we know that it's dormant 23 tumors -- 24 Q. That's okay. I'm just trying to 25 understand the, you know, the definition of 12:03 PM</p>

<p style="text-align: right;">Page 467</p> <p>1 dormancy that you're using and I wanted --</p> <p>2 I'll stop there.</p> <p>3 And then my question is, Doctor,</p> <p>4 you're talking about an effect of NDMA on</p> <p>5 existing tumors. Yes? Is that right? 12:04 PM</p> <p>6 A. So a dormant tumor is different</p> <p>7 from a tumor. A dormant tumor -- and how we</p> <p>8 know this is basing in autopsy patients from</p> <p>9 car accidents, is that --</p> <p>10 Q. Right. 12:04 PM</p> <p>11 A. -- a certain percentage of people,</p> <p>12 if -- in a car accident -- of someone who</p> <p>13 died of a car accident, they didn't die of</p> <p>14 their cancer, you resection their -- it could</p> <p>15 be their prostate, their breast or thyroid, a 12:04 PM</p> <p>16 pathologist can see signs of dormancy.</p> <p>17 And then when we studied those</p> <p>18 dormant tumors in models, we see that they're</p> <p>19 proliferating, they're alive but they're not</p> <p>20 growing. 12:04 PM</p> <p>21 So a dormant tumor, by definition,</p> <p>22 is a tumor that's not growing but they're --</p> <p>23 there's evidence of something that's either</p> <p>24 dysplastic or hyperplasia, but we know from</p> <p>25 studies that there are dormant tumors in many 12:05 PM</p>	<p style="text-align: right;">Page 469</p> <p>1 "sleeping"?</p> <p>2 MR. NIGH: Form objection.</p> <p>3 BY MR. FOWLER:</p> <p>4 Q. In order for something to be</p> <p>5 called to be dormant -- in order for a tumor 12:05 PM</p> <p>6 to be called dormant, it must be capable of</p> <p>7 waking up, correct?</p> <p>8 MR. NIGH: Form objection.</p> <p>9 A. And that's -- dormant tumors can</p> <p>10 be awakened if there's a trigger of dormancy 12:05 PM</p> <p>11 escape, and that's where we get into the key</p> <p>12 characteristics and the processes that can</p> <p>13 awaken a tumor.</p> <p>14 Q. Right. Right.</p> <p>15 Doctor, I believe we previously 12:06 PM</p> <p>16 marked Exhibit 5, which is your report from</p> <p>17 Actos. Would you like to turn to that,</p> <p>18 please?</p> <p>19 A. Yes.</p> <p>20 MR. NIGH: And just for the 12:06 PM</p> <p>21 record, we believe that this is not</p> <p>22 available on the public record.</p> <p>23 MR. FOWLER: Okay. So you're</p> <p>24 welcome to deem it confidential. We</p> <p>25 will or whatever you want to do. 12:06 PM</p>
<p style="text-align: right;">Page 468</p> <p>1 difference types of tissues.</p> <p>2 Q. Yes, sir. You would agree that</p> <p>3 dormant comes from the Latin word "sleeping,"</p> <p>4 right?</p> <p>5 MR. NIGH: Form objection. 12:05 PM</p> <p>6 MR. FOWLER: Is there a problem</p> <p>7 with that question, Counsel?</p> <p>8 MR. NIGH: Sure.</p> <p>9 MR. FOWLER: What's the problem</p> <p>10 with that question? 12:05 PM</p> <p>11 MR. NIGH: Weighted.</p> <p>12 MR. FOWLER: What?</p> <p>13 MR. NIGH: Weighted. It's a</p> <p>14 weighted question.</p> <p>15 MR. FOWLER: It's a weighted 12:05 PM</p> <p>16 question.</p> <p>17 MR. NIGH: Yeah.</p> <p>18 MR. FOWLER: I've never heard that</p> <p>19 objection before.</p> <p>20 MR. NIGH: That is one. 12:05 PM</p> <p>21 MR. FOWLER: That's cool. Learned</p> <p>22 a new one.</p> <p>23 BY MR. FOWLER:</p> <p>24 Q. Doctor, do you agree that the term</p> <p>25 "dormant" comes from the latin word 12:05 PM</p>	<p style="text-align: right;">Page 470</p> <p>1 MR. NIGH: I think there may be</p> <p>2 some more complications other than just</p> <p>3 that, but we have to see what you're</p> <p>4 asking.</p> <p>5 MR. FOWLER: Fair enough. It's 12:06 PM</p> <p>6 the Doctor's -- fair enough.</p> <p>7 BY MR. FOWLER:</p> <p>8 Q. Doctor, if you turn -- and get</p> <p>9 your report out too, please, at the same</p> <p>10 time. You can use the exhibit that we 12:07 PM</p> <p>11 marked -- whichever one you have.</p> <p>12 A. I have it.</p> <p>13 Q. Okay. Turn to the Actos report</p> <p>14 page 4 and turn to your report, page 1.</p> <p>15 Are you on page -- I'll give you a 12:07 PM</p> <p>16 you second there.</p> <p>17 A. Yes.</p> <p>18 Q. On page 1, do you see your</p> <p>19 sentence, "As an academic scientist, I am</p> <p>20 committed to research efforts that are 12:07 PM</p> <p>21 focused on preventing and finding a cure for</p> <p>22 cancer. I am motivated and dedicated to</p> <p>23 discovering inno --</p> <p>24 A. Oh, you're on the first paragraph.</p> <p>25 Q. Yes, sir. 12:07 PM</p>

<p style="text-align: right;">Page 471</p> <p>1 "Innovative approaches to</p> <p>2 answering important biological questions that</p> <p>3 impact carcinogenesis in humans."</p> <p>4 Do you see that, sir?</p> <p>5 A. Yes. 12:08 PM</p> <p>6 Q. Now turn to Actos pages 4 and 5.</p> <p>7 Do you see that exact same</p> <p>8 sentence?</p> <p>9 A. On page -- which page?</p> <p>10 Q. It goes to 4 to 5. It's at the 12:08 PM</p> <p>11 bottom of 5.</p> <p>12 A. Yes.</p> <p>13 Q. Okay. If you look at page --</p> <p>14 Actos report page 28; valsartan report page</p> <p>15 34. 12:08 PM</p> <p>16 A. Yes.</p> <p>17 Q. You have the same chart -- the</p> <p>18 same figure appears in both -- identically in</p> <p>19 both reports, correct?</p> <p>20 A. Yes. 12:08 PM</p> <p>21 Q. So when you were preparing your</p> <p>22 valsartan report, you had your Actos report</p> <p>23 available to you and you borrowed from that,</p> <p>24 correct?</p> <p>25 MR. NIGH: Form objection. 12:09 PM</p>	<p style="text-align: right;">Page 473</p> <p>1 250-page report, there are certain concepts</p> <p>2 that haven't changed from Actos in 2014 to</p> <p>3 this report.</p> <p>4 BY MR. FOWLER:</p> <p>5 Q. I'm not talking about concepts. 12:10 PM</p> <p>6 I'm actually talking exact verbiage.</p> <p>7 You literally took sentences,</p> <p>8 whole cloth from the Actos report and dropped</p> <p>9 them into your valsartan report, didn't you,</p> <p>10 sir. 12:10 PM</p> <p>11 MR. NIGH: Form objection.</p> <p>12 A. So I -- that's one sentence in a</p> <p>13 250-page report that explains what I do,</p> <p>14 which is a generic statement.</p> <p>15 BY MR. FOWLER: 12:10 PM</p> <p>16 Q. Turn to Actos report page 19.</p> <p>17 Valsartan report page 33.</p> <p>18 A. Yep. 19 and 33.</p> <p>19 Q. If you look at the -- in Actos you</p> <p>20 see the paragraph, you start, "However, even 12:11 PM</p> <p>21 though the classic model of initiation,</p> <p>22 promotion, progression."</p> <p>23 Do you see that section?</p> <p>24 A. Sure.</p> <p>25 Q. And the sentence goes on, "The 12:11 PM</p>
<p style="text-align: right;">Page 472</p> <p>1 A. This is a figure that I have,</p> <p>2 that's my figure that I use for multiple --</p> <p>3 to explain the tumor microenvironment, which</p> <p>4 is very important. That cancer is not just a</p> <p>5 genetic process, that tumor microenvironment 12:09 PM</p> <p>6 plays an important role. This is a figure</p> <p>7 that -- part of explaining that process, I</p> <p>8 use this figure.</p> <p>9 BY MR. FOWLER:</p> <p>10 Q. Right. But the sentence that you 12:09 PM</p> <p>11 copied identically, you literally took that</p> <p>12 from the Actos record and dropped that same</p> <p>13 sentence in the valsartan reports, right?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. Which sentence? 12:09 PM</p> <p>16 BY MR. FOWLER:</p> <p>17 Q. The one we looked at before, on</p> <p>18 page 1 and page 4 to 5 -- page 1 of</p> <p>19 valsartan, 4 to 5. We just looked at it.</p> <p>20 A. Yes. 12:09 PM</p> <p>21 Q. Okay. You literally cut and</p> <p>22 pasted that from Actos into valsartan, right?</p> <p>23 MR. NIGH: Form objection.</p> <p>24 A. Well, that's -- that's an</p> <p>25 important concept that is true, and in my 12:10 PM</p>	<p style="text-align: right;">Page 474</p> <p>1 picture of cancer is a cell autonomous</p> <p>2 disease."</p> <p>3 Do you see where I am there?</p> <p>4 A. On the Actos report?</p> <p>5 Q. Yep. 12:11 PM</p> <p>6 A. Yes.</p> <p>7 Q. Valsartan page 33, do we see the</p> <p>8 same -- you changed pictured idea that the</p> <p>9 cancer is a cell autonomous?</p> <p>10 MR. NIGH: Form objection. 12:12 PM</p> <p>11 A. I don't see the exact sentence.</p> <p>12 Where are you --</p> <p>13 BY MR. FOWLER:</p> <p>14 Q. Let me --</p> <p>15 A. It says -- my report -- 12:12 PM</p> <p>16 Q. I'll withdraw the question,</p> <p>17 Doctor. Just forget that question, please.</p> <p>18 I've got a bad note.</p> <p>19 Please turn on Actos page 34,</p> <p>20 Actos report page 34, and valsartan page 212, 12:12 PM</p> <p>21 valsartan report page 212.</p> <p>22 A. Yep.</p> <p>23 Q. On page 212 that you're looking</p> <p>24 at, do you see the sentence, "Moreover, long</p> <p>25 latency periods reviewed as hallmark of 12:13 PM</p>

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<p style="text-align: right;">Page 475</p> <p>1 cancer causation, a genotoxic carcinogen such 2 as cigarette smoke"? 3 A. Are you in Actos? 4 Q. I said 212, valsartan? 5 A. Sorry, what sentence -- 12:13 PM 6 Q. "Moreover, long latency" -- 7 A. Oh, yes. 8 THE REPORTER: Hold on, gentlemen. 9 We need one at a time. We're talking 10 over a lot. 12:13 PM 11 MR. FOWLER: Apologies. 12 THE REPORTER: I'm kind of losing 13 you guys. 14 BY MR. FOWLER: 15 Q. Do you see that sentence, sir? 12:13 PM 16 A. The "Moreover, long latency"? 17 Q. Yes. And then Actos on page 34, 18 do you see that exact same sentence? 19 A. Yes. 20 Q. And so do you acknowledge that you 12:13 PM 21 had the Actos report available to you and you 22 borrowed language from it in the places we've 23 discussed, language and images that we 24 discussed? 25 MR. NIGH: Form objection. 12:14 PM</p>	<p style="text-align: right;">Page 477</p> <p>1 concepts. 2 Q. Yes, sir. I'm not talking about 3 concepts. I'm talking about the actual 4 sentence. 5 Do you acknowledge that you cut 12:15 PM 6 and pasted or do you -- is it your testimony 7 it's a coincidence that you used the exact 8 same words and commas in the two reports in 9 those sentences? 10 MR. NIGH: Hold on. Form 12:15 PM 11 objection. 12 BY MR. FOWLER: 13 Q. And let me try to ask the question 14 again. 15 My question is simply, where we 12:15 PM 16 see the identical sentences, is it your 17 testimony it is simply coincidental because 18 the topics are the same, or do you 19 acknowledge that you took from your -- 20 literally took from your Actos report when 12:16 PM 21 preparing your valsartan report? 22 MR. NIGH: Form objection. 23 A. As I said before, when I do 24 similar concept and even when I'm writing 25 papers and reviews, I have certain concepts 12:16 PM</p>
<p style="text-align: right;">Page 476</p> <p>1 A. The concepts of -- that I mention 2 in the Actos report of how a nongenotoxic 3 carcinogen promote cancer and the key 4 characteristics that IARC has done, are the 5 same key characteristics that I talk about in 12:14 PM 6 valsartan. 7 BY MR. FOWLER: 8 Q. Right. 9 A. There may be some overlapping 10 concepts and a few identical sentence. In a 12:14 PM 11 250-page report, sometimes you -- with a 12 similar concept, such as Actos can stimulate 13 tumor dormancy via inflammation or 14 angiogenesis, a carcinogen such as NDMA can 15 also stimulate inflammation and angiogenesis. 12:14 PM 16 So in a 250-page report, there may 17 be a few sentences that were -- the concept 18 is -- here the concepts are very similar. 19 As a tumor promoter, NDMA in the 20 valsartan can act as a tumor promoter by 12:15 PM 21 stimulating inflammation and angiogenesis, 22 and this is in the dormancy escape section, 23 that concept of stimulating inflammation 24 angiogenesis was what I was talking about in 25 the Actos, so there is some overlap in the 12:15 PM</p>	<p style="text-align: right;">Page 478</p> <p>1 that I have written. And this particular 2 concept was written in the Actos report, but 3 in a 250-page report, it would -- it's not 4 surprising that a sentence here and there may 5 be similar to a sentence here in the Actos 12:16 PM 6 report because these are similar concepts 7 that -- 8 BY MR. FOWLER: 9 Q. And you knew they were similar 10 concepts when you began writing your 12:16 PM 11 valsartan report, right? 12 MR. NIGH: Form objection. 13 A. So when I started to do my 14 independent peer-reviewed research of does 15 NDMA or NDEA cause cancer, one of the 12:16 PM 16 processes I looked at are the mechanisms of 17 action; and as IARC has said, of the 10 key 18 characteristics, to stimulate inflammation, 19 chronic inflammation, angiogenesis, that is 20 one of the key characteristics, so that was 12:17 PM 21 part of what I had to investigate. And in 22 the Actos case, that was a similar mechanism. 23 BY MR. FOWLER: 24 Q. My question was simply this: Were 25 you aware, when you prepared your valsartan 12:17 PM</p>

37 (Pages 475 - 478)

<p style="text-align: right;">Page 479</p> <p>1 report, that you had similar concepts in your 2 Actos report? Did you recall that at the 3 time or not? 4 A. Yes. 5 Q. Okay. 12:17 PM 6 A. Yes. 7 Q. And did you -- 8 A. When it comes to inflammation 9 angiogenesis. 10 Q. Perfect. Fine. Sticking to that. 12:17 PM 11 Did you then consult your Actos 12 report for language that you liked or 13 references that you liked and brought them 14 into the valsartan report? Did you do that, 15 sir? It's okay. 12:17 PM 16 MR. NIGH: Form objection. 17 A. So what I'm saying is that not 18 only the Actos report is -- I have concepts 19 and figures that explain inflammation and 20 angiogenesis that aren't just specific to the 12:18 PM 21 Actos report. We're talking about how a 22 tumor -- how inflammation can act as a tumor 23 promoter for a particular chemical, whether 24 it's Actos or in this case NDMA or NDEA, 25 there are concepts I have that are similar to 12:18 PM</p>	<p style="text-align: right;">Page 481</p> <p>1 A. I focused on papers that were 2 specific for valsartan and NDMA. I didn't -- 3 I did not -- I didn't think ranitidine 4 epidemiology studies -- I focused on studies 5 that were NDMA and -- 12:20 PM 6 Q. Maybe my question wasn't good. 7 Are you aware that there were 8 studies of NDMA in ranitidine? Are you aware 9 of that? 10 MR. NIGH: Form objection. 12:20 PM 11 A. Yes, as part of my -- like I said, 12 I read papers that aren't in my report, and 13 part of it I am aware that -- of NDMA is not 14 only in valsartan but other drugs. 15 BY MR. FOWLER: 12:20 PM 16 Q. Okay. Have you been retained in 17 any other litigation related to NDMA besides 18 valsartan? 19 A. No. 20 Q. Okay. 12:20 PM 21 MR. FOWLER: I'm going to pass the 22 witness. Thank you, sir. You're still 23 on the hook. We have questions coming. 24 MR. FOWLER: And I think what we'd 25 like to do, take a quick -- nobody needs 12:20 PM</p>
<p style="text-align: right;">Page 480</p> <p>1 whatever I am writing. 2 So I have multiple reviews on 3 tumor dormancy, on angiogenesis inflammation. 4 Those concepts are in all the reviews that we 5 have. I've studied angiogenesis for 30 12:18 PM 6 years, so this is a concept that I've been 7 studying since 1990, for 30 years. 8 Q. Okay. Thank you. You can set 9 those aside, Doctor. 10 Doctor, are you aware of reports 12:18 PM 11 of ranitidine contamination with NDMA? 12 A. Yes. 13 Q. And are you aware that there are 14 many epidemiological studies specifically 15 designed to test the hypothesis that NDMA and 12:19 PM 16 ranitidine increases risk of cancer outcomes? 17 Are you aware of those? 18 MR. NIGH: Hold on. Form 19 objection. 20 A. So I've only focused on this 12:19 PM 21 question specific to valsartan. So I haven't 22 studied epidemiology studies for ranitidine. 23 BY MR. FOWLER: 24 Q. Why did you review dietary NDMA 25 studies but not the ranitidine studies? 12:19 PM</p>	<p style="text-align: right;">Page 482</p> <p>1 to leave the room. We're going to move 2 the TV so you can see the questioner and 3 they can see you. 4 What I might suggests, it's up to 5 counsel. I can just get out of my seat 12:21 PM 6 and trade seats with you and then -- 7 let's go off the record. 8 THE VIDEOGRAPHER: The time is 9 12:21. We're off the record. 10 (Recess taken at 12:21 p.m. to 12:45 p.m.) 12:21 PM 11 THE VIDEOGRAPHER: The time is 12 12:45. We're back on is record. 13 EXAMINATION 14 BY MR. TRISCHLER: 15 Q. Doctor, good afternoon. 12:46 PM 16 A. Good afternoon. 17 Q. My name is Clem Trischler. I 18 represent the Mylan defendants in this 19 litigation. I'm going to follow up on some 20 of the questions that have been asked of you 12:46 PM 21 by Mr. Fowler. Okay? 22 A. Great. 23 Q. You told us that you relied on the 24 Hidajat study to support your opinion that 25 nitrosamine exposures cause cancer in humans, 12:46 PM</p>

<p style="text-align: right;">Page 483</p> <p>1 correct?</p> <p>2 A. My opinion is on NDMA and --</p> <p>3 Q. All right. I'll be more precise.</p> <p>4 You told us that you relied on the</p> <p>5 Hidajat study to support your opinion that 12:46 PM</p> <p>6 NDMA exposure causes cancers in humans,</p> <p>7 correct?</p> <p>8 A. Correct.</p> <p>9 Q. As we've already established,</p> <p>10 Hidajat was an occupational study of factory 12:46 PM</p> <p>11 workers in the rubber industry, true?</p> <p>12 A. True.</p> <p>13 Q. The route of administration or the</p> <p>14 route of exposure to NDMA among the factory</p> <p>15 workers was inhalation, correct? 12:47 PM</p> <p>16 A. Correct.</p> <p>17 Q. And as I recall, the stated</p> <p>18 purpose of that study was to evaluate cancer</p> <p>19 mortality risks associated with occupational</p> <p>20 exposures to rubber dust, rubber fumes and 12:47 PM</p> <p>21 nitrosamines, correct?</p> <p>22 A. Correct.</p> <p>23 Q. And as Hidajat observed, rubber</p> <p>24 workers are exposed to a host of potential</p> <p>25 carcinogens in addition to NDMA, correct? 12:47 PM</p>	<p style="text-align: right;">Page 485</p> <p>1 nitrosamines that they looked at.</p> <p>2 A. Yes, then correct.</p> <p>3 Q. But the point I was trying to get</p> <p>4 at is, they did not consider it a confounding</p> <p>5 contribution or risk of carcinogens such as 12:49 PM</p> <p>6 benzene or nathylamine; is that correct?</p> <p>7 A. When they calculated the risks of</p> <p>8 cancer mortality, they quantified the NDMA</p> <p>9 exposure using quartiles. So they related</p> <p>10 the amount of NDMA that these workers were 12:49 PM</p> <p>11 exposed to to the cancer mortality.</p> <p>12 Q. I know what they did with respect</p> <p>13 to NDMA. I asked you a different question.</p> <p>14 Let me see if I can try it again.</p> <p>15 Did the authors of the Hidajat 12:49 PM</p> <p>16 study consider the confounding contribution</p> <p>17 of risks for carcinogens such as benzene or</p> <p>18 nathylamine, both of which are prevalent in</p> <p>19 the rubber industry.</p> <p>20 A. I don't believe they looked at 12:49 PM</p> <p>21 benzene.</p> <p>22 Q. And another notable limitation of</p> <p>23 the Hidajat study is that the authors were</p> <p>24 not able or did not have the ability to</p> <p>25 control for smoking or other lifestyle 12:50 PM</p>
<p style="text-align: right;">Page 484</p> <p>1 A. Correct.</p> <p>2 Q. But some of those other</p> <p>3 carcinogens represent potential confounding</p> <p>4 exposures. Would you agree?</p> <p>5 A. Yes. However, Hidajat quantified 12:47 PM</p> <p>6 the amount of NDMA using four different</p> <p>7 quartiles to relate to the cancer mortality.</p> <p>8 Q. I understand that.</p> <p>9 But he also noted and observed</p> <p>10 that there were other -- that every subject 12:47 PM</p> <p>11 in that study was exposed to carcinogens --</p> <p>12 other carcinogens in addition to NDMA, right?</p> <p>13 A. Correct.</p> <p>14 Q. Hidajat found cancer risks</p> <p>15 associated with rubber dust, correct? 12:48 PM</p> <p>16 A. Yes.</p> <p>17 Q. Hidajat found cancer risks</p> <p>18 associated with rubber fumes, true?</p> <p>19 A. Correct.</p> <p>20 Q. And in the study, Hidajat -- the 12:48 PM</p> <p>21 authors of the Hidajat study look only at</p> <p>22 rubber dust, rubber fumes, and nitrosamines</p> <p>23 correct?</p> <p>24 A. They also looked at NDMA.</p> <p>25 Q. I'm including NDMA as one of the 12:48 PM</p>	<p style="text-align: right;">Page 486</p> <p>1 factors, correct?</p> <p>2 A. Correct, yes.</p> <p>3 Q. But nevertheless, in your report,</p> <p>4 you provide us with cumulative exposure data</p> <p>5 for NDMA from the Hidajat study, right? 12:50 PM</p> <p>6 A. Correct.</p> <p>7 Q. And I think it's at page 87 of</p> <p>8 your report, if you have it in front of you,</p> <p>9 the second full paragraph there, you suggest</p> <p>10 that workers in Quartile II had cumulative 12:50 PM</p> <p>11 exposure to 7,488 micrograms, correct?</p> <p>12 A. Yes.</p> <p>13 Q. That's -- that translates to</p> <p>14 7,488,000 nanograms, true?</p> <p>15 A. Yes. 12:51 PM</p> <p>16 Q. And workers in Quartile III,</p> <p>17 according to you and your interpretation of</p> <p>18 the Hidajat data, had cumulative exposures to</p> <p>19 14,304 micrograms, correct?</p> <p>20 A. Correct. 12:51 PM</p> <p>21 Q. And that translates to 14,304,000</p> <p>22 nanograms?</p> <p>23 A. Correct.</p> <p>24 Q. And in Quartile IV, the workers in</p> <p>25 the Hidajat study had cumulative exposure to 12:51 PM</p>

<p style="text-align: right;">Page 487</p> <p>1 23,208 micrograms of NDMA, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And, again, simple math tells us</p> <p>4 that that translate to 23,208,000 nanograms</p> <p>5 of NDMA, to which the workers in Quartile IV 12:51 PM</p> <p>6 were exposed, right?</p> <p>7 A. Yes.</p> <p>8 Q. In looking at your report, you did</p> <p>9 not provide any calculation of cumulative</p> <p>10 exposure for Quartile I; is that true? 12:52 PM</p> <p>11 A. Yes. Quartile I was the baseline</p> <p>12 of the background.</p> <p>13 Q. And that baseline -- that baseline</p> <p>14 exposure, then, was less -- was less than the</p> <p>15 7,488 micrograms. Is that what I understand 12:52 PM</p> <p>16 that to be then?</p> <p>17 A. Correct.</p> <p>18 Q. Did anyone in Quartile I have an</p> <p>19 increased risk of cancer in the Hidajat</p> <p>20 study? 12:52 PM</p> <p>21 A. So what Hidajat compared, and they</p> <p>22 did actually -- you had brought up smoking.</p> <p>23 They did comment on they thought had they</p> <p>24 adjusted smoking it wouldn't have made a</p> <p>25 difference. 12:52 PM</p>	<p style="text-align: right;">Page 489</p> <p>1 right?</p> <p>2 A. Correct.</p> <p>3 Q. So workers in that study were</p> <p>4 thought to be exposed to other nitrosamines</p> <p>5 as well, right? 12:54 PM</p> <p>6 A. Correct.</p> <p>7 Q. In fact, Hidajat talks about other</p> <p>8 nitrosamines that were prevalent in the</p> <p>9 rubber industry, including NMOR, right?</p> <p>10 A. Right. In rubber dust, NDMA is 12:54 PM</p> <p>11 the most highest and -- the highest</p> <p>12 concentration of a nitrosamine in rubber</p> <p>13 dust.</p> <p>14 Q. We can talk about that, perhaps,</p> <p>15 if we have additional time. But what I'm 12:54 PM</p> <p>16 interested in trying to make clear and trying</p> <p>17 to understand, is that all the workers in the</p> <p>18 Hidajat occupational study were exposed to</p> <p>19 other nitrosamines in addition to NDMA.</p> <p>20 We know that for a fact, right? 12:55 PM</p> <p>21 A. Correct.</p> <p>22 Q. And Hidajat actually went so far</p> <p>23 as to calculate a total nitrosamine score for</p> <p>24 the individuals in Quartiles II, III and IV,</p> <p>25 correct? 12:55 PM</p>
<p style="text-align: right;">Page 488</p> <p>1 And what they did was compare</p> <p>2 Quartile II, III and IV to Quartile I, was</p> <p>3 the comparison.</p> <p>4 Q. So in Hidajat, is it your</p> <p>5 understanding in that study there's no effort 12:53 PM</p> <p>6 made to determine whether cumulative exposure</p> <p>7 to something less than 7 1/2 million</p> <p>8 nanograms over a lifetime would cause an</p> <p>9 increased risk of cancer; that wasn't the</p> <p>10 analysis that Hidajat did, right? 12:53 PM</p> <p>11 A. Correct. My understanding is that</p> <p>12 they were comparing this increased exposure</p> <p>13 to NDMA and using increased exposure from</p> <p>14 Quartile II to Quartile III was even higher,</p> <p>15 to Quartile IV was even higher, was that each 12:53 PM</p> <p>16 comparison was to Quartile I.</p> <p>17 Q. Right. So what they were looking</p> <p>18 at was whether there's an increasing risk of</p> <p>19 cancer at exposure levels above 7 1/2 million</p> <p>20 nanograms, agreed? 12:53 PM</p> <p>21 A. Correct.</p> <p>22 Q. And -- now, the numbers that you</p> <p>23 gave us for cumulative exposures from Hidajat</p> <p>24 we just talked about were strictly cumulative</p> <p>25 exposures to NDMA in that rubber industry, 12:54 PM</p>	<p style="text-align: right;">Page 490</p> <p>1 A. Correct. Yes.</p> <p>2 Q. The -- and that total nitrosamine</p> <p>3 score was even higher than the cumulative</p> <p>4 numbers that you reported to us for NDMA,</p> <p>5 right? 12:55 PM</p> <p>6 A. Yes.</p> <p>7 Q. I think if you look at -- do you</p> <p>8 have the Hidajat paper in front of you or do</p> <p>9 you need me to --</p> <p>10 A. Yes, I have it. 12:55 PM</p> <p>11 Q. Okay. Great.</p> <p>12 I think if you go to -- might be</p> <p>13 the second to the last page. It's the last</p> <p>14 page of Table 2 there, so looking at the</p> <p>15 material down at the bottom. 12:56 PM</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. All right. And it's there, where</p> <p>19 Hidajat documents the total nitrosamine</p> <p>20 scores for occupational exposures of workers 12:56 PM</p> <p>21 in Quartiles II, III and IV, right?</p> <p>22 A. Yes.</p> <p>23 Q. And what he says is that, in</p> <p>24 Quartile II, the total nitrosamines exposure</p> <p>25 for these workers is on the order of 12:56 PM</p>

<p style="text-align: right;">Page 491</p> <p>1 something greater than 10.03 micrograms, 2 right? 3 A. Yes. 4 Q. And in Quartile III, the exposure 5 is between 10.03 to 21.8 micrograms? 12:56 PM 6 A. I'm not following where you are. 7 Q. The footnotes -- 8 A. Oh, at the footnote. 9 Q. -- down at the bottom of the page, 10 the Hidajat's paper we were talking about. 12:57 PM 11 A. Yes, the exposure Quartile I? 12 Q. Right. Correct. 13 A. Yes. 14 Q. Then you see Quartile II with the 15 exposure of 10.0 to 21.38. You see that? 12:57 PM 16 A. Yes. 17 Q. Quartile III lists 2138 to 442? 18 A. Yes. 19 Q. And usually the same calculations 20 and assumptions and methodology that you put 12:57 PM 21 in your report, you can calculate a total 22 cumulative nitrosamine exposure for the 23 rubber workers based on that data that 24 Hidajat just gave us, right? 25 A. Correct. 12:58 PM</p>	<p style="text-align: right;">Page 493</p> <p>1 51,000 to 1 million micrograms, using the 2 same assumptions and methodology that you 3 used in your report, correct? 4 MR. NIGH: Form objection. 5 A. Yes. 12:59 PM 6 BY MR. TRISCHLER: 7 Q. So, in this -- by the way, have 8 you ever looked at any of the medical records 9 for any of the plaintiffs in this litigation? 10 A. No. 01:00 PM 11 Q. Have you looked at any of the 12 pharmacy records for any of the plaintiffs in 13 this litigation? 14 A. Yes, I did have files on the 15 amount of NDMA in the valsartan tablets. 01:00 PM 16 Q. Okay. Perhaps my question wasn't 17 clear. So I apologize for that. 18 I was not asking you about testing 19 information that you may have received on 20 nitrosamine levels that were found in some 01:00 PM 21 valsartan. I was asking about patient 22 pharmacy records showing what medications a 23 given patient received and when and from 24 whom. That's what I was referring to as 25 pharmacy records 01:00 PM</p>
<p style="text-align: right;">Page 492</p> <p>1 Q. And that's what you did in your 2 report for purposes of looking at cumulative 3 NDMA exposure, correct? 4 A. Correct. 5 Q. You took the NDMA calculation that 12:58 PM 6 Hidajat gave and made assumptions for hours 7 of employment, work weeks, work weeks and 8 breathing rates, correct? 9 A. Correct. 10 Q. And if we apply those same 12:58 PM 11 assumptions to the total nitrosamine score 12 for cumulative exposures, the cumulative 13 nitrosamine in Quartile II, the numbers that 14 we get are on the order of 24,000 to 51,000 15 micrograms, correct? 12:59 PM 16 MR. NIGH: Form objection. 17 A. Yeah, I would have to calculate it 18 out. But yeah, I would agree it's a similar 19 calculation times the 48 weeks per year, 40 20 hours per -- you know, work per day and the 12:59 PM 21 breathing rate. 22 BY MR. FOWLER: 23 Q. Right. And it's just a math 24 problem and in Quartile III cumulative 25 nitrosamine exposure would be on the order of 12:59 PM</p>	<p style="text-align: right;">Page 494</p> <p>1 A. You mean specific patients? 2 Q. Correct. 3 A. No. No, I didn't get specific 4 patient -- I just had from different types of 5 manufacturers. 01:01 PM 6 Q. Right. I think we're on the same 7 page, but let me try to ask the question 8 again just so that we're clear and just so we 9 have a clean record. 10 In your work in this case, did you 01:01 PM 11 look at any patient pharmacy records to 12 evaluate what any given plaintiff -- what 13 medications any given plaintiff took and in 14 what quantity and for what duration? 15 A. No. 01:01 PM 16 Q. And I know from listening to your 17 answers to Mr. Fowler's questions that you 18 have a medical degree, correct? 19 A. Yes, correct. 20 Q. You're not a licensed physician, 01:01 PM 21 though, true? 22 A. Correct. 23 Q. And since you're not a licensed 24 physician, I take it you've not treated or 25 examined any of the plaintiffs to this 01:01 PM</p>

<p style="text-align: right;">Page 495</p> <p>1 litigation, correct?</p> <p>2 A. Correct.</p> <p>3 Q. In your connection with your work</p> <p>4 in this case, have you taken a medical or</p> <p>5 prescription history from any plaintiff in 01:02 PM</p> <p>6 this litigation?</p> <p>7 A. I'm sorry, I missed the question.</p> <p>8 Q. I said in connection with your</p> <p>9 work in this case, have you taken a medical</p> <p>10 history or a prescription history from any 01:02 PM</p> <p>11 plaintiff in this litigation?</p> <p>12 A. No.</p> <p>13 Q. Have you reviewed any depositions</p> <p>14 of any plaintiffs in this litigation?</p> <p>15 A. No. 01:02 PM</p> <p>16 Q. Can you identify a single</p> <p>17 plaintiff in this litigation who ingested 23</p> <p>18 million nanograms of NDMA or NDEA from a</p> <p>19 valsartan-containing medication?</p> <p>20 A. Can you repeat that again? Sorry. 01:02 PM</p> <p>21 Q. Sure. Can you identify a single</p> <p>22 plaintiff by name in this litigation who</p> <p>23 ingested 23 million nanograms of NDMA or NDEA</p> <p>24 from a valsartan-containing medication?</p> <p>25 A. Yeah, I didn't go through specific 01:03 PM</p>	<p style="text-align: right;">Page 497</p> <p>1 20,000 nanograms, this patient would reach</p> <p>2 Quartile II in about 300 days, approximately</p> <p>3 10 months. And that doesn't take into</p> <p>4 account the amount of NDMA in the diet.</p> <p>5 MR. TRISCHLER: Object and move to 01:05 PM</p> <p>6 strike as nonresponsive.</p> <p>7 BY MR. TRISCHLER:</p> <p>8 Q. I didn't ask you what was in your</p> <p>9 report, and I didn't ask you what the testing</p> <p>10 showed. 01:05 PM</p> <p>11 My question was: Can you name for</p> <p>12 me a plaintiff, an individual who took</p> <p>13 valsartan containing 188 parts per million at</p> <p>14 the maximum dose for 300 days? Is there any</p> <p>15 such person out there that you are aware of? 01:05 PM</p> <p>16 A. So I had a list of the amounts of</p> <p>17 NDMA in the different tablets from the</p> <p>18 different sources. So I'm not totally</p> <p>19 understanding the question.</p> <p>20 Q. I'm asking you -- then let me ask 01:05 PM</p> <p>21 it a third time. Help you.</p> <p>22 Can you name an individual</p> <p>23 plaintiff who you claim actually took</p> <p>24 valsartan-containing medication that</p> <p>25 contained 188 parts per million of valsartan 01:05 PM</p>
<p style="text-align: right;">Page 496</p> <p>1 names. In my report I went through -- I</p> <p>2 calculated the levels of NDMA and compared</p> <p>3 them to the levels that the FDA allowed; and</p> <p>4 then compared them to amounts that were in</p> <p>5 the different diet study. So I didn't -- I 01:03 PM</p> <p>6 think we're on the same page. I didn't go</p> <p>7 into specific patients.</p> <p>8 Q. I largely understand what's in</p> <p>9 your report, that's why I didn't ask you</p> <p>10 about that, sir. I asked you a different 01:03 PM</p> <p>11 even question, and I'd like an answer to it.</p> <p>12 Did you -- are you capable or</p> <p>13 able to identify a single plaintiff to this</p> <p>14 litigation who was exposed to 23 million</p> <p>15 nanograms of NDMA from valsartan-containing 01:04 PM</p> <p>16 medication?</p> <p>17 A. I'll just read from -- so -- my</p> <p>18 report. So there are levels, for example,</p> <p>19 ZHP API levels are 188.1 part per million,</p> <p>20 and ZHP007991345, and I wrote "If the 188.1 01:04 PM</p> <p>21 part per million were made into 320 milligram</p> <p>22 tablets, these tablets would approximate</p> <p>23 60,000 nanograms of NDMA."</p> <p>24 And then I get into if a patient</p> <p>25 taking the 320 milligrams were to ingest 01:04 PM</p>	<p style="text-align: right;">Page 498</p> <p>1 for every day for 300 days; do you know</p> <p>2 anyone either at that level -- of actual</p> <p>3 level of exposure; and if so, I want to know</p> <p>4 their name.</p> <p>5 MR. NIGH: Form objection. 01:06 PM</p> <p>6 A. So my understanding is this in a</p> <p>7 pharmacy where people had different valsartan</p> <p>8 tablets. So there was a mixture of different</p> <p>9 amounts.</p> <p>10 So I don't -- if you're asking -- 01:06 PM</p> <p>11 I don't know specific names of anyone. My</p> <p>12 understanding is that there's different</p> <p>13 tablets that have different amounts of NDMA</p> <p>14 [sic]. And so as I said in my report, I took</p> <p>15 the amounts that I had -- that were 01:06 PM</p> <p>16 documented in these valsartan tablets, and I</p> <p>17 did a range.</p> <p>18 The high was 188.1. There were</p> <p>19 lower amounts, and there was a range of</p> <p>20 anywhere from 170- to 200-fold higher amounts 01:06 PM</p> <p>21 of the NDMA. For example, just a little</p> <p>22 earlier -- I think -- you have the report so</p> <p>23 you know all this. Like, for example, the</p> <p>24 65.1 part per million for D5191, 63.4 part</p> <p>25 per million for product code, and 56.7 part 01:07 PM</p>

<p style="text-align: right;">Page 499</p> <p>1 per million for product code c55523, 2 and these are all way above the FDA 3 allowable -- acceptable intake for NDMA. 4 Q. Do you remember what my question 5 was, sir? 01:07 PM 6 A. I don't know an individual -- I 7 answered -- I don't know by name a particular 8 person, I think. 9 Q. There you go. Thank you. 10 Now, the workers in Quartile II in 01:07 PM 11 the Hidajat study had total nitrosamines 12 exposures between 24 million to 51 million 13 nanograms, right? 14 A. I would have to calculate it out, 15 but it seems reasonable that it's a similar 01:08 PM 16 calculation that I used in my report for 17 NDMA. 18 Q. Well, we've been talking in 19 generalities. So let me see if I can get 20 specific and maybe that will help us. 01:08 PM 21 Do you agree that the occupational 22 exposures in Hidajat, where workers were 23 exposed for years and years and years to tens 24 of millions of nanograms of nitrosamines, is 25 not at all representative of the nitrosamine 01:08 PM</p>	<p style="text-align: right;">Page 501</p> <p>1 A. Correct. 2 Q. And, in fact, I think if you take 3 a look at page 10 of your report, that's 4 where we'll find a mention of my client, 5 right? 01:10 PM 6 A. Yes. Yes. 7 Q. And at page 10 of your report, one 8 of the things you suggest is that Mylan had 9 NDMA ranging from .01 parts per million to 10 .09 parts per million that was reported." 01:10 PM 11 Did I read that correctly? 12 A. Yes. 13 Q. So if we assume that someone was 14 taking Mylan's valsartan at the maximize 15 daily dose of 320 milligrams per day, the 01:11 PM 16 NDMA content in that medication was no more 17 than 3 to 28 nanograms per day, correct? 18 MR. NIGH: Form objection. 19 A. Correct. 20 BY MR. TRISCHLER: 01:11 PM 21 Q. That's far below the acceptable 22 intake level of 96 nanograms set by the FDA, 23 though, right? 24 A. Correct. My understanding is -- 25 Q. By the way, when we were talking 01:11 PM</p>
<p style="text-align: right;">Page 500</p> <p>1 levels observed in the valsartan-containing 2 medications at issue? Can we agree on that 3 simple fact? 4 A. Well, as said in my report, I 5 quantified the amount of -- using the Hidajat 01:09 PM 6 paper and their quartiles and the 7 calculation, I quantified the amount of NDMA 8 that those rubber workers were exposed to. 9 And this was a study with 36,000 people over 10 a 49-year follow up 01:09 PM 11 Q. Okay. Then let's -- if you're not 12 able to give me a simple yes to that then 13 maybe we can get specific. 14 I told you I represent Mylan. 15 You're familiar with my client, right? 01:09 PM 16 A. Yes. 17 Q. You reviewed data from testing 18 that was conducted to determine nitrosamine 19 levels in some of Mylan's 20 valsartan-containing medications, right? 01:09 PM 21 A. Correct. 22 Q. And you've been -- you discussed 23 that data in your report and you've mentioned 24 it a few times in response to some of my 25 questions here today, right? 01:10 PM</p>	<p style="text-align: right;">Page 502</p> <p>1 about Hidajat and we mentioned that the 2 exposures in Hidajat were on the order of 3 tens of millions of nanograms, that was a 4 cumulative yearly exposure not over a 5 lifetime, right? 01:11 PM 6 MR. NIGH: Form objection. 7 A. Correct. My understanding is that 8 there are people who had -- they went to the 9 pharmacy and had different -- different 10 valsartan batches, so there was not only 01:11 PM 11 Mylan, they may have gone to the pharmacy and 12 then gotten another valsartan tablet from a 13 different -- 14 BY MR. TRISCHLER: 15 Q. Well, in fairness, sir, you told 01:12 PM 16 me you haven't reviewed any patient day, you 17 haven't reviewed any medical records, you 18 haven't talked to any patient, you haven't 19 looked at any pharmacy records, you're just 20 speculating right now. 01:12 PM 21 MR. NIGH: Form objection. 22 BY MR. TRISCHLER: 23 Q. Right? 24 A. Okay. I'm not following the 25 question, though. 01:12 PM</p>

<p style="text-align: right;">Page 503</p> <p>1 Q. Well, let's stick to the question.</p> <p>2 Let's stick to the specific facts that I'm</p> <p>3 asking about.</p> <p>4 Any exposure to nitrosamines from</p> <p>5 Mylan's valsartan-containing medications 01:12 PM</p> <p>6 comes nowhere close to approaching the levels</p> <p>7 that were reported in Hidajat.</p> <p>8 Can we agree on that?</p> <p>9 MR. NIGH: Form objection.</p> <p>10 A. Yes. 01:12 PM</p> <p>11 BY MR. TRISCHLER:</p> <p>12 Q. All right. And we talked about</p> <p>13 NDMA. Your report, at page 10, suggests that</p> <p>14 you've seen testing materials suggesting --</p> <p>15 or that provided you with information about 01:13 PM</p> <p>16 NDEA content in some of Mylan's medication,</p> <p>17 right?</p> <p>18 A. Correct.</p> <p>19 Q. And I think what you suggest in</p> <p>20 your report, is that the NDEA content from 01:13 PM</p> <p>21 testing of commercialized API lots from Mylan</p> <p>22 were found to range from somewhere between</p> <p>23 .01 parts per million to a high of 1.57 parts</p> <p>24 per million.</p> <p>25 That's what you wrote, right? 01:13 PM</p>	<p style="text-align: right;">Page 505</p> <p>1 we're on a time. I've detailed this in my</p> <p>2 report, so I won't go into details.</p> <p>3 But the mechanism of action -- not</p> <p>4 only is it a potent carcinogen causing cancer</p> <p>5 in all these animals, but the mechanism of 01:14 PM</p> <p>6 action of that potent electrophilic DNA</p> <p>7 adduct, that -- NDA has a very similar</p> <p>8 mechanism of action as NDMA.</p> <p>9 And then I spent a good part of my</p> <p>10 report, with the first 150 pages, on the 01:15 PM</p> <p>11 mechanism of action of NDMA and the 9 key</p> <p>12 characteristics. And then I went in through</p> <p>13 my report, NDEA also has nine of those key</p> <p>14 characteristics.</p> <p>15 And, in fact, scientists -- and we 01:15 PM</p> <p>16 use it in our own lab every day. We use</p> <p>17 these NDEA actually to stimulate oxidative</p> <p>18 stress, which is one of the key</p> <p>19 characteristics of cancer, and we use it to</p> <p>20 initiate cancer growth. And multiple labs 01:15 PM</p> <p>21 throughout the country used to start -- it</p> <p>22 can initiate esophageal cancer, liver cancer.</p> <p>23 So, basically, the bottom line is</p> <p>24 I use NDEA, the mechanisms of action, and the</p> <p>25 activity as a carcinogen are very similar to 01:15 PM</p>
<p style="text-align: right;">Page 504</p> <p>1 A. Yes.</p> <p>2 Q. In your work in this case, have</p> <p>3 you made any attempt to calculate the mean</p> <p>4 NDEA levels observed in all lots of</p> <p>5 commercialized API tested by Mylan? 01:13 PM</p> <p>6 A. So in the NDA [sic] -- I didn't</p> <p>7 calculate the NDA -- the answer is I did not</p> <p>8 calculate the amount of NDEA. What I rely on</p> <p>9 in my report is that the mechanism of action</p> <p>10 of NDA -- because we have so much evidence 01:13 PM</p> <p>11 that NDA is a potent carcinogen in animals</p> <p>12 and that the mechanism of action of NDA is</p> <p>13 highly similar to NDMA.</p> <p>14 So my first 150 pages of my report</p> <p>15 are dedicated to NDMA. And NDEA I relied on 01:14 PM</p> <p>16 a lot of the similar -- in fact, a lot of the</p> <p>17 studies are overlapping, where they look at</p> <p>18 both NDMA and NDEA, and they have similar</p> <p>19 mechanisms of action. They both are very</p> <p>20 potent carcinogens. 01:14 PM</p> <p>21 In fact, NDEA is three times more</p> <p>22 potent in certain animal studies than NDMA;</p> <p>23 and, in fact, NDEA can cause cancer in about</p> <p>24 60 substrains of mice and about 32 -- about</p> <p>25 10 substrains of rats, and I won't -- I know 01:14 PM</p>	<p style="text-align: right;">Page 506</p> <p>1 NDMA.</p> <p>2 Q. Do you remember the rather simple,</p> <p>3 straightforward question that I asked you?</p> <p>4 A. I think I started and said that</p> <p>5 the answer was I didn't calculate NDEA 01:16 PM</p> <p>6 concentrations.</p> <p>7 Q. All right. All I asked you was,</p> <p>8 in connection with your work in this case,</p> <p>9 have you received information about NDEA</p> <p>10 levels in Mylan's commercialized API, did you 01:16 PM</p> <p>11 make any attempt to calculate a mean</p> <p>12 concentration?</p> <p>13 A. So -- no, because the epi studies</p> <p>14 said I relied on, occupational with Hidajat</p> <p>15 and the diet studies, I focused on NDMA, 01:16 PM</p> <p>16 which was -- they had evidence on NDMA. The</p> <p>17 only NDEA study that I cited for epi, as you</p> <p>18 know in the report, was the Zhejiang case</p> <p>19 with pancreatic cancer.</p> <p>20 Q. Other than Zhejiang, there are no 01:16 PM</p> <p>21 epidemiology studies on NDEA that you found?</p> <p>22 A. Correct.</p> <p>23 Q. And so what you told me, although</p> <p>24 I didn't quite ask it, but what you told me</p> <p>25 was that you didn't calculate a mean 01:17 PM</p>

<p style="text-align: right;">Page 507</p> <p>1 concentration from the API commercialized</p> <p>2 lots produced by Mylan. Your focus, as it</p> <p>3 related to NDEA, was looking at mechanism of</p> <p>4 action, right?</p> <p>5 A. Well, just to clarify, I didn't 01:17 PM</p> <p>6 calculate the NDEA levels from the</p> <p>7 occupational studies and the Hidajat. But I</p> <p>8 calculated the NDEA levels, you know, that's</p> <p>9 in the report, from these -- from page 10,</p> <p>10 these concentrations are in the report. 01:17 PM</p> <p>11 Q. Well, didn't you just tell me that</p> <p>12 your focus when it came to NDEA was looking</p> <p>13 at mechanism of action?</p> <p>14 A. Well, to clarify, there were --</p> <p>15 the levels of NDEA were still highly above -- 01:18 PM</p> <p>16 the levels of NDEA that are in these</p> <p>17 valsartan tablets that I wrote here are</p> <p>18 higher than the FDA approved level, and</p> <p>19 that's what I was talking about in the</p> <p>20 report. 01:18 PM</p> <p>21 Q. Did you ever look at FDA's testing</p> <p>22 of Mylan's finished dose product?</p> <p>23 A. No, I don't have that.</p> <p>24 Q. Are you aware that the results of</p> <p>25 Mylan's FDA testing on finished dose products 01:18 PM</p>	<p style="text-align: right;">Page 509</p> <p>1 A. So the data I had documented</p> <p>2 levels of NDMA, NDEA in the different</p> <p>3 valsartan manufacturer -- in the different</p> <p>4 manufacturers.</p> <p>5 Q. Right. I understand that. 01:20 PM</p> <p>6 I said did you ask or do anything</p> <p>7 to validate that data or to determine if</p> <p>8 there was other more reliable data in terms</p> <p>9 of the actual concentrations in Mylan's</p> <p>10 finished dose product? 01:20 PM</p> <p>11 A. So I was -- I was asked does NDMA</p> <p>12 and NDEA cause cancer as a general causation.</p> <p>13 I wasn't asked for a particular patient, a</p> <p>14 specific example -- a specific patient who</p> <p>15 took a particular valsartan. 01:20 PM</p> <p>16 As I said before, my understanding</p> <p>17 was, and this is what I document in the</p> <p>18 report, that there are different levels.</p> <p>19 ZHP, you know, very high, and some of these</p> <p>20 other ones are lower. So this is the -- I 01:20 PM</p> <p>21 base this on -- I was asked does NDMA, NDEA,</p> <p>22 are they human carcinogens?</p> <p>23 Q. I understand what you were tasked</p> <p>24 to do. I think you probably said that 20</p> <p>25 times over the last two days, sir. 01:21 PM</p>
<p style="text-align: right;">Page 508</p> <p>1 are even lower than the concentrations that</p> <p>2 you itemized in your report?</p> <p>3 A. So as you have here, I have the</p> <p>4 Mylan MDL 2875 that I relied on and said that</p> <p>5 the NDEA range from 0.1 to 1.57 part per 01:18 PM</p> <p>6 million, and the FDA acceptable index is</p> <p>7 0.083 part per million.</p> <p>8 Q. Yeah, I know what you relied on.</p> <p>9 You already told me that three time.</p> <p>10 My question was, were you aware 01:19 PM</p> <p>11 that there was FDA testing done on Mylan's</p> <p>12 product that showed that the actual</p> <p>13 concentrations in finished dose were lower</p> <p>14 than what you reported on page 10 of your</p> <p>15 report? 01:19 PM</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A. No.</p> <p>18 BY MR. TRISCHLER:</p> <p>19 Q. Why did you ignore or not report</p> <p>20 on FDA's finished dose testing Mylan's 01:19 PM</p> <p>21 product?</p> <p>22 A. I didn't have -- I didn't have</p> <p>23 that data. And what I was -- I only could</p> <p>24 report on the data that I had access to.</p> <p>25 Q. Did you ask for other data? 01:19 PM</p>	<p style="text-align: right;">Page 510</p> <p>1 My question to you is very</p> <p>2 specific. And that was, did you do anything</p> <p>3 to validate whether the Mylan numbers that</p> <p>4 you report on page 10 of your report are</p> <p>5 accurate or if there is additional data with 01:21 PM</p> <p>6 respect to finished dose testing, suggesting</p> <p>7 that the levels are even lower than what you</p> <p>8 reported? You either did something or you</p> <p>9 didn't.</p> <p>10 MR. NIGH: Form objection. 01:21 PM</p> <p>11 BY MR. TRISCHLER:</p> <p>12 Q. What's the answer?</p> <p>13 A. I did not.</p> <p>14 Q. All right. And you made a</p> <p>15 statement yesterday that I found notable, and 01:21 PM</p> <p>16 I'm sure I'll come back to it. And I think</p> <p>17 what you told us is that scientists don't</p> <p>18 cherry-pick data. Agreed?</p> <p>19 A. Correct.</p> <p>20 Q. A good scientist should always 01:22 PM</p> <p>21 look at and consider all the facts, right?</p> <p>22 A. Correct.</p> <p>23 Q. And if you wanted to consider all</p> <p>24 the facts, one of the things that you can --</p> <p>25 and if you wanted to determine whether or not 01:22 PM</p>

<p style="text-align: right;">Page 511</p> <p>1 the dose and duration of a exposure from</p> <p>2 Mylan's valsartan-containing medications can</p> <p>3 cause cancer, one of the things you could do</p> <p>4 is to calculate the mean exposure from test</p> <p>5 data that's available, right? 01:22 PM</p> <p>6 MR. NIGH: Form objection</p> <p>7 A. Correct.</p> <p>8 BY MR. TRISCHLER:</p> <p>9 Q. You never did that?</p> <p>10 A. Well, I wasn't asked to 01:22 PM</p> <p>11 differentiate by -- between ZHP, Torrent and</p> <p>12 Mylan, the exact amounts of NDMA from each</p> <p>13 one in a specific -- for a specific patient,</p> <p>14 for a specific person.</p> <p>15 Q. Right. And since you weren't 01:23 PM</p> <p>16 asked to do it, you didn't do it?</p> <p>17 A. Correct.</p> <p>18 Q. And so since you didn't calculate</p> <p>19 a mean from the test data, I'll represent to</p> <p>20 you, and I'll ask you to assume as an expert, 01:23 PM</p> <p>21 that the mean concentration for Mylan's test</p> <p>22 data that you cite is .47 parts per million.</p> <p>23 Okay?</p> <p>24 A. Correct.</p> <p>25 Q. And so accepting that as true, the 01:23 PM</p>	<p style="text-align: right;">Page 513</p> <p>1 the cumulative nitrosamine exposure seen by</p> <p>2 the workers in Hidajat, right?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. Well, as I said before, I</p> <p>5 didn't -- I went into NDMA specifically not 01:25 PM</p> <p>6 nitrosamine concentration. So I was focused</p> <p>7 on NDMA.</p> <p>8 BY MR. TRISCHLER:</p> <p>9 Q. Right. And you understand I'm</p> <p>10 allowed to ask you different questions? 01:25 PM</p> <p>11 A. Yeah, yeah, I agree.</p> <p>12 Q. So that's what I'm doing. And</p> <p>13 it's simple math, Doctor.</p> <p>14 If we assume a nitrosamine</p> <p>15 exposure from medication of 54,000 nanograms, 01:25 PM</p> <p>16 we know in Hidajat that the workers in</p> <p>17 Quartile II were exposed annually to 23</p> <p>18 million nanograms of nitrosamines, correct?</p> <p>19 MR. NIGH: Form objection.</p> <p>20 A. Correct. 01:25 PM</p> <p>21 BY MR. TRISCHLER:</p> <p>22 Q. And so the math tells us that</p> <p>23 someone taking Mylan's valsartan at the mean</p> <p>24 concentration observed for a full year, would</p> <p>25 see an increase in their -- would see a 01:25 PM</p>
<p style="text-align: right;">Page 512</p> <p>1 maximum daily exposure to a patient that was</p> <p>2 taking a 320 milligram tablet, would be about</p> <p>3 150 nanograms per day, correct?</p> <p>4 A. Correct.</p> <p>5 Q. And so if someone took Mylan's 01:23 PM</p> <p>6 valsartan every day for a year, that</p> <p>7 hypothetical person would have been exposed</p> <p>8 to 54,750 nanograms of NDEA, correct?</p> <p>9 A. Correct. But as I said before,</p> <p>10 when people go to the pharmacy, they're 01:24 PM</p> <p>11 getting different batches of valsartan over</p> <p>12 their time when they're taking the drug,</p> <p>13 so...</p> <p>14 Q. Well, I'm not asking about any --</p> <p>15 I'm not asking about any plaintiffs because 01:24 PM</p> <p>16 you don't have any information on any</p> <p>17 plaintiffs. I'm asking about a</p> <p>18 hypothetical -- this hypothetical that I'm</p> <p>19 asking you to assume. Okay?</p> <p>20 A. Okay. Yes. 01:24 PM</p> <p>21 Q. So if someone takes Mylan's</p> <p>22 valsartan for a year and is exposed to 54,750</p> <p>23 nanograms of nitrosamines, what we know, from</p> <p>24 your own study, from your own report, is that</p> <p>25 that concentration is about .002 percent of 01:24 PM</p>	<p style="text-align: right;">Page 514</p> <p>1 nitrosamine exposure to about .002 percent of</p> <p>2 what was seen by the workers in Hidajat.</p> <p>3 Simple math, right?</p> <p>4 A. If they were only taking the</p> <p>5 Mylan, yes. 01:26 PM</p> <p>6 Q. And the reality is then --</p> <p>7 THE REPORTER: I'm sorry, Counsel,</p> <p>8 I didn't get that.</p> <p>9 "And the reality is?"</p> <p>10 Q. That the exposure to nitrosamines 01:26 PM</p> <p>11 from Mylan's valsartan-containing medication,</p> <p>12 is a minute fraction of the nitrosamine</p> <p>13 exposures that were seen in Hidajat.</p> <p>14 Can we agree on that?</p> <p>15 A. As I said before, I focused on the 01:26 PM</p> <p>16 NDMA -- on the NDMA levels in the -- in</p> <p>17 Hidajat, not the total nitrosamines. If this</p> <p>18 is a hypothetical question, then correct.</p> <p>19 Q. And the bottom line is that</p> <p>20 there's nothing in Hidajat to suggest that 01:27 PM</p> <p>21 consuming 150 nanograms per day of</p> <p>22 nitrosamines will lead to an increased</p> <p>23 risk of cancer; is that correct?</p> <p>24 A. Of total nitrosamines, was your</p> <p>25 question? 01:27 PM</p>

<p style="text-align: right;">Page 515</p> <p>1 Q. Let me ask it again because I want 2 to be clear. 3 There is absolutely nothing in the 4 Hidajat study to suggest that consuming 150 5 nanograms of nitrosamines a day will lead to 01:27 PM 6 an increased risk of cancer, is there? 7 A. Like I said, I would have to go 8 through the calculations. If it's a similar 9 calculation of what I did with NDMA, and 10 then -- well, yes, it's similar reasoning 01:28 PM 11 with the calculation. 12 Q. Right. Because you don't need to 13 do any calculations to answer this question, 14 Doctor, if we're being -- if we're being 15 honest and we're looking at all the facts and 01:28 PM 16 all the evidence, which you told me a good 17 scientist does. Hidajat didn't talk about 18 the impact of small incremental increases in 19 nitrosamine loads, right? 20 MR. NIGH: Form objection. 01:28 PM 21 BY MR. TRISCHLER: 22 Q. That was not even the subject of 23 that paper. 24 MR. NIGH: Form objection. 25 A. So when I -- in my report, I 01:28 PM</p>	<p style="text-align: right;">Page 517</p> <p>1 what the authors of the Hidajat paper did, 2 was to compare the increased risk of cancer 3 among workers in Quartile I with those in 4 Quartiles II, III, and IV, right? 5 A. Correct. And that's what I wrote 01:30 PM 6 in my report. 7 Q. And the workers in Quartile I had 8 a baseline exposure to 7 million nanograms of 9 NDEA on a yearly basis, right? 10 A. So when they did the comparisons 01:30 PM 11 between Quartile II, III and IV to Quartile 12 I, in the 10 different cancers that I 13 documented there was a significant increase 14 in risk of that cancer. 15 Q. When comparing individuals that 01:31 PM 16 had a baseline exposure of 7 million 17 nanograms to individuals that had a baseline 18 exposure to 25 to 50 million nanograms every 19 year, right? 20 A. Yes. They compared Quartile II to 01:31 PM 21 I, and then Quartile III to I, and then 22 Quartile IV to I, and seven of the 10 cancers 23 had a significant trend increase between II, 24 III, and IV versus I, and then in three of 25 the cancers, in two of the blood cancers and 01:31 PM</p>
<p style="text-align: right;">Page 516</p> <p>1 didn't rely only on Hidajat, I relied -- 2 / 3 BY MR. TRISCHLER: 4 Q. I didn't ask you if you relied on 5 anything else. 01:29 PM 6 What I asked you was, in Hidajat, 7 the authors of that paper never claim that 8 small incremental increases in nitrosamine 9 exposure on the order of 150 nanograms per 10 day is going to lead to an increased risk of 01:29 PM 11 cancer. They never set out to answer that 12 question; they never made that claim; and 13 that wasn't even the purpose of the paper. 14 Can we agree on that? 15 A. For my -- the purpose of this 01:29 PM 16 paper in the context of my report is that 17 rubber dust isn't the rubber dust or the 18 total nitrosamines. I focused on quantifying 19 the levels of NDMA in the study. So 20 that's -- I focused on those quartiles with 01:29 PM 21 NDMA, not the total nitrosamines and the 22 other factors they looked at. 23 Q. Well, you missed my question with 24 that answer, so that's probably my fault. 25 What you told me earlier was that 01:30 PM</p>	<p style="text-align: right;">Page 518</p> <p>1 liver, I believe, they went to Quartile III, 2 and Quartile III versus I was significant and 3 Quartile IV versus I was significant. 4 In all of these study, it's only 5 NDMA. They quantified the amount of NDMA in 01:31 PM 6 each of the quartiles. 7 Q. So nowhere in the Hidajat paper do 8 the authors ever attempt to make the claim 9 that a small increase of daily exposure 10 of nitro -- to NDMA on the order of 100, 200, 01:32 PM 11 300 nanograms per day is going to lead to an 12 increase risk of cancer. 13 Do they make that claim, yes or 14 no. 15 MR. NIGH: Form objection. 01:32 PM 16 A. I don't -- they do not. 17 BY MR. TRISCHLER: 18 Q. Right. And one thing we can agree 19 upon, Doctor, is that if the occupational 20 exposures in Hidajat were in orders of 01:32 PM 21 magnitude greater than what any plaintiff 22 taking Mylan's valsartan-containing 23 medication was ever confronted with. 24 Can we agree on that? 25 MR. NIGH: Form objection. 01:32 PM</p>

<p style="text-align: right;">Page 519</p> <p>1 A. So, yeah, in my report I did 2 compare the amounts that they would have 3 exposed to through the tablets and that was 4 on the order of anywhere 180 to 200, so I 5 agree it was much higher. 01:33 PM 6 And Hidajat -- in epidemiology 7 study there are limitations. So -- and 8 you've mentioned a couple of them. But the 9 strength of this particular epidemiology 10 study, as you know, is 35,000, 36,000 people, 01:33 PM 11 a long follow up. But it was -- it actually 12 underestimated the amount of cancer of 13 mortality, because people also developed 14 cancer and don't die, and they use cancer 15 mortality as the readout. 01:33 PM 16 So as in any epidemiology study, 17 there are strengths and limitations. And 18 you've mentioned some of the limitations. 19 MR. TRISCHLER: Object and move 20 to strike at nonresponsive. 01:33 PM 21 BY MR. TRISCHLER: 22 Q. I didn't ask you about the 23 limitations of the study, nor did I ask you 24 about comparisons that you made of other 25 manufacturer's product to the levels observed 01:33 PM</p>	<p style="text-align: right;">Page 521</p> <p>1 you know, to say it's everywhere, you know, 2 it's commonly in -- yeah, in the air, water, 3 food. I mean, I assume you're talking about 4 that. 5 Q. Have you ever written that 01:35 PM 6 nitrosamines are ubiquitous? 7 A. I would have to look. I've 8 written a lot of things. Like I said, in 9 this case -- nitrosamines has a class of, you 10 know, over 200 different compounds. So, you 01:35 PM 11 know, like 80 percent of them can cause 12 cancer and 15 are reasonably anticipated. 13 But yes, so I -- yes, they can be expressed. 14 Q. What does that mean, "they could 15 be expressed"? I'm not sure I understand 01:36 PM 16 what you're telling me. 17 A. Well -- okay. I agree that they 18 can be ubiquitous. 19 Q. And they're ubiquitous because 20 they're present in the air we breathe, the 01:36 PM 21 water we drink, and the foods we eat, right? 22 A. Correct. 23 Q. And the fact -- I believe you 24 cited a paper. I'm just going to read this, 25 quote -- you tell me if you are familiar with 01:36 PM</p>
<p style="text-align: right;">Page 520</p> <p>1 in Hidajat. I asked you about Mylan. 2 A. Sorry. I missed the question 3 then. 4 MR. NIGH: Hold on. I would 5 object to the colloquy. You actually 01:34 PM 6 asked about patients who have taken 7 Mylan. 8 BY MR. TRISCHLER: 9 Q. Can we agree that the exposures 10 reported by authors of the Hidajat paper, are 01:34 PM 11 on orders of magnitude far greater than any 12 amounts of nitrosamines ever reported in any 13 of Mylan's valsartan-containing medications? 14 A. So I would agree with that, with 15 the data I've seen, but I -- yes. 01:34 PM 16 Q. We all know nitrosamines are 17 ubiquitous, correct? 18 MR. NIGH: Form objection. 19 A. I assume you mean in the body. 20 Are you talking about -- yes. 01:34 PM 21 BY MR. TRISCHLER: 22 Q. No, in nature, in the world. What 23 does -- 24 A. Yes. Yeah, but as a scientist, 25 you know, we look -- ubiquitous is a very -- 01:35 PM</p>	<p style="text-align: right;">Page 522</p> <p>1 it. 2 "Nitrosamines are ubiquitous in the 3 human environment and have been detected in 4 food items, including cured meats, bacon, 5 fish and beer, cosmetics, drugs and even the 01:36 PM 6 front passenger areas of new cars." 7 Do you remember reading that 8 statement? 9 A. So yes, nitrosamines can be -- I 10 agree, yes. Like I said before, ours focused 01:37 PM 11 more on NDMA, the specific nitrosamine rather 12 than as a class, but... 13 Q. Do you agree with that statement 14 that I just read? 15 A. Yes. Yes. 01:37 PM 16 Q. So you and I can agree, then, that 17 all of us are exposed to nitrosamines, 18 including NDMA and NDEA on a daily basis, 19 right? 20 A. Correct. 01:37 PM 21 Q. And every day we're exposed to 22 those nitrosamines, right? 23 A. Correct. 24 Q. Every day we metabolize those 25 nitrosamines, correct? 01:37 PM</p>

<p style="text-align: right;">Page 523</p> <p>1 A. Yes.</p> <p>2 Q. And every day we eliminate them?</p> <p>3 A. Yes.</p> <p>4 Q. Have you ever personally</p> <p>5 participated in any study or done any 01:37 PM</p> <p>6 original research that's been published to</p> <p>7 estimate daily exposures to NDMA or NDEA?</p> <p>8 A. No.</p> <p>9 Q. Okay. Prior to this case, have</p> <p>10 you ever participated in any research to try 01:38 PM</p> <p>11 and determine the range of exogenous</p> <p>12 exposures to nitrosamines across a given</p> <p>13 population base?</p> <p>14 A. No.</p> <p>15 Q. As part of your work in this case, 01:38 PM</p> <p>16 did you attempt to do any sort of survey of</p> <p>17 the literature to determine if there was a</p> <p>18 known or recognized range for exogenous</p> <p>19 exposures to nitrosamines?</p> <p>20 A. So, as I mentioned in the case, 01:38 PM</p> <p>21 we, as like many other labs in the world, use</p> <p>22 NDMA and NDEA in our lab to cause cancer in</p> <p>23 animals, and we use it to induce oxidative</p> <p>24 stress. We use it to -- one of our lab</p> <p>25 findings, as other labs have shown, that the 01:38 PM</p>	<p style="text-align: right;">Page 525</p> <p>1 Q. Page 32 of your report, you note</p> <p>2 that NDMA is found in beer, cured meats,</p> <p>3 bacon, smoked and salted fish, and cheeses.</p> <p>4 Do you see that?</p> <p>5 A. Yes. 01:40 PM</p> <p>6 Q. And then you go on to suggest that</p> <p>7 estimated daily dietary intake of NDMA ranges</p> <p>8 from .03 to .08 micrograms.</p> <p>9 Do you see that?</p> <p>10 A. Yes. 01:40 PM</p> <p>11 Q. And in your report you cite a</p> <p>12 single source for that estimate, papered by</p> <p>13 Hrudey, correct?</p> <p>14 A. Yes.</p> <p>15 Q. And I think that paper is titled 01:40 PM</p> <p>16 "Drinking Water as a Proportion of Total</p> <p>17 Human Exposure to Volatile Nitrosamines."</p> <p>18 Did I get that right?</p> <p>19 A. Yes.</p> <p>20 Q. Do you have a copy of that paper 01:41 PM</p> <p>21 with you? If not, I can put it up.</p> <p>22 A. I think I do have it. Sorry.</p> <p>23 There's a lot of papers.</p> <p>24 Q. Why don't we just put it up. It</p> <p>25 might be quicker and easier. 01:41 PM</p>
<p style="text-align: right;">Page 524</p> <p>1 cell death can stimulate tumor growth. So we</p> <p>2 use NDMA and NDEA to stimulate cell death in</p> <p>3 the lab.</p> <p>4 So we do use NDMA and NDEA in</p> <p>5 laboratories, just like many laboratories 01:39 PM</p> <p>6 throughout the world.</p> <p>7 Q. Well, thank you for that</p> <p>8 explanation. I don't think that's what I was</p> <p>9 asking you, though.</p> <p>10 My question was, in connection 01:39 PM</p> <p>11 with your work in this litigation, did you</p> <p>12 make -- do any attempt to survey the</p> <p>13 literature to determine if there were known</p> <p>14 reported or recognized ranges for exogenous</p> <p>15 exposures to NDMA? 01:39 PM</p> <p>16 A. Yes, that was part of my research,</p> <p>17 to see what -- so as I mentioned in my</p> <p>18 report, so in the diet there's a certain</p> <p>19 range, it could be .03 to .06 microgram per</p> <p>20 kilogram or in alcohol there can be NDMA. So 01:39 PM</p> <p>21 in diet, there's a certain amount that you</p> <p>22 can get of the NDMA.</p> <p>23 Q. All right. Well, then, go to page</p> <p>24 32 of your report, if you don't mind.</p> <p>25 A. Yes. 01:40 PM</p>	<p style="text-align: right;">Page 526</p> <p>1 MR. TRISCHLER: Let's have the</p> <p>2 Hrudey paper marked as our next</p> <p>3 sequential exhibit.</p> <p>4 (Exhibit 28, Drinking Water as a Proportion</p> <p>5 of Total Human Exposure to Volatile 01:40 PM</p> <p>6 N-Nitrosamines, marked for identification.)</p> <p>7 Q. So what we're looking at right now</p> <p>8 is the -- on screen, it's the first page of</p> <p>9 the Hrudey paper, correct, Doctor?</p> <p>10 A. Yes. 01:42 PM</p> <p>11 Q. And this is -- you can confirm for</p> <p>12 us this is the paper that you cite in your</p> <p>13 expert report that you did in this case,</p> <p>14 true?</p> <p>15 A. True. 01:42 PM</p> <p>16 Q. And you found this article to be</p> <p>17 reliable and authoritative, at least with</p> <p>18 respect to its estimates of exogenous NDMA</p> <p>19 intake from food, correct?</p> <p>20 A. Correct. 01:42 PM</p> <p>21 Q. And you cite it favorably in terms</p> <p>22 of estimating amount of nitrosamine ingested</p> <p>23 on a daily basis from food, water and</p> <p>24 beverages, right?</p> <p>25 A. Right. I mean, other people do 01:42 PM</p>

<p style="text-align: right;">Page 527</p> <p>1 cite a little different amounts and, you 2 know, every has different -- they're not 3 exactly the same, but I thought this was a 4 reasonable one.</p> <p>5 Q. Well, that's what I was going to 01:43 PM 6 get at. So you sort of anticipated where I 7 was going.</p> <p>8 Since you never personally 9 researched or studied daily dietary intake of 10 nitrosamines before this case, what did you 01:43 PM 11 do to validate Hrudey's estimate of daily 12 intake levels as compared to other levels 13 that are reported in the scientific 14 literature?</p> <p>15 A. Well, as part of my background 01:43 PM 16 reading, I compared it to what's known, like 17 the EPA has certain limits, even New Jersey 18 has a certain limit of NDMA in the water, 19 that's a little different than California, 20 and, like, California is the 10 nanogram per 01:43 PM 21 ml.</p> <p>22 So is your question what's the 23 allowable safe level of NDMA? Maybe I'm 24 missing the question.</p> <p>25 Q. No. What I'm getting at is you 01:43 PM</p>	<p style="text-align: right;">Page 529</p> <p>1 Gushgari, G-u-s-h-g-a-r-i? 2 / 3 (Exhibit 29, Critical review of major 4 sources of human exposure to N-nitrosamines, 5 marked for identification.) 01:45 PM 6 MR. TRISCHLER: Can you highlight 7 the abstract for the benefit of witness 8 and myself and others? Thank you.</p> <p>9 THE WITNESS: Yep, I see it.</p> <p>10 BY MR. TRISCHLER: 01:45 PM 11 Q. So in your review of 500-plus 12 articles that you undertook to prepare for 13 this case, did you review Gushgari's paper? 14 A. I don't recall reviewing this 15 particular one. But, like I said, we review 01:45 PM 16 hundreds of papers that I -- you know, 17 through the course of the evaluation period.</p> <p>18 Q. Okay. But if we look at it now, 19 what we can see is that Gushgari estimates 20 daily exogenous exposure to nitrosamines to 01:46 PM 21 be in the range of 2,000 nanograms to 25,000 22 nanograms, depending upon whether the 23 individual is a smoker, right? 24 A. Correct.</p> <p>25 Q. So according to Gushgari at least, 01:46 PM</p>
<p style="text-align: right;">Page 528</p> <p>1 already told me that Hrudey provided an 2 estimate of daily nitrosamine consumption 3 from food, water and beverages, right? 4 A. Yes. This was for a dietary, yes, 5 food. 01:44 PM 6 Q. And that estimate was on the order 7 of .06 to .08 micrograms per day, right? 8 MR. NIGH: Form objection. 9 A. Yeah, it was .03 to .06. And then 10 if you included beer, according to them, it 01:44 PM 11 was .08 micrograms per day.</p> <p>12 BY MR. TRISCHLER: 13 Q. Okay. And what I was getting at 14 was, and I think you alluded to this, is that 15 you recognize there are lots of other studies 01:44 PM 16 in the literature that would suggest that 17 exogenous NDMA intake from diet is far higher 18 than the estimates that Hrudey made? 19 A. Correct. And that's why, when I 20 went in the epi studies, I picked the epi 01:44 PM 21 studies especially that focused -- or that 22 quantified the amount of NDMA in their study.</p> <p>23 Q. So, for instance -- 24 MR. TRISCHLER: Can we put up the 25 next exhibit, which will be a paper from 01:45 PM</p>	<p style="text-align: right;">Page 530</p> <p>1 tobacco usually accounts for about 22,000 2 nanograms per day of nitrosamine intake, 3 correct? 4 A. Correct.</p> <p>5 Q. Food accounts for roughly 2000 01:46 PM 6 nanograms? 7 A. Yes. Well, actually -- I'm sorry. 8 I'm just reading it.</p> <p>9 THE REPORTER: We had some talking 10 over, so I didn't get your question 01:46 PM 11 counsel.</p> <p>12 A. Sorry, I'm just reading -- it 13 looks like food and beverage is 6.7 nanogram 14 per gram. I'm just reading from the 15 abstract. 01:46 PM 16 BY MR. TRISCHLER: 17 Q. So it says food was -- about three 18 quarters of the way down -- 1900 nanograms 19 plus or minus three.</p> <p>20 Do you see that? 01:47 PM 21 A. Oh, okay. The pictures are 22 blocking some of it, but I can see the 1900. 23 I can't see the food, but I take your -- 24 MR. NIGH: You can't take his word 25 for it. He's asking if you see it. You 01:47 PM</p>

<p style="text-align: right;">Page 531</p> <p>1 got to actually see it. You can't just 2 take his word for it. 3 THE WITNESS: The pictures are 4 blocking -- okay, now I can see it. 5 Okay. Yes, food, 1900. 01:47 PM 6 BY MR. TRISCHLER: 7 Q. All right. And alcohol 8 contributes another thousand nanograms, 9 correct? 10 A. Yes. 01:47 PM 11 Q. Again, these estimates were 12 reported by Gushgari in his paper. 13 Do you have a recollection, 14 sitting here today, whether you actually 15 reviewed this paper as part of your work in 01:48 PM 16 this case? 17 A. Well part of -- this is total 18 nitrosamine exposure. I focused on the human 19 epi studies that actually quantified the NDMA 20 concentrations rather than the total 01:48 PM 21 nitrosamine exposure. So I don't recall this 22 particular study, and I wouldn't be 23 surprised, because I focus more on the 24 specific NDMA and NDEA specifically rather 25 than total nitrosamines. 01:48 PM</p>	<p style="text-align: right;">Page 533</p> <p>1 Gushgari were reasonable and he considered 2 them to be accurate. 3 Do you have any reason to disagree 4 with Dr. Hecht's conclusions? 5 A. No. 01:50 PM 6 MR. NIGH: Form objection. 7 BY MR. TRISCHLER: 8 Q. Aside from this paper from 9 Gushgari that we've been talking about that 10 provides estimates of daily exogenous 01:50 PM 11 nitrosamine intake on the order of 2,000 to 12 25,000 nanograms per day, are you aware of 13 any other estimates in the literature of 14 daily nitrosamine intake? 15 A. As I mentioned, I focused on NDMA 01:50 PM 16 rather than total nitrosamines. So I really 17 didn't go into total nitrosamine exposure, 18 because that wasn't the question I was asked. 19 Q. I understand what the question you 20 were asked. 01:50 PM 21 I just asked you, are you aware of 22 any others -- any other papers that provide 23 an estimate of daily nitrosamine exogenous 24 intake? 25 A. Offhand -- so -- because this is 01:51 PM</p>
<p style="text-align: right;">Page 532</p> <p>1 Q. Do you know Stephen Hecht, 2 H-e-c-h-t? 3 A. I don't know him personally. I 4 know, you know, of his work. 5 Q. Do you know him by reputation? 01:48 PM 6 A. Somewhat. 7 Q. What do you know of Dr. Hecht's 8 work? 9 A. Well, we just went over it 10 yesterday. He was on the nitrosamines -- the 01:49 PM 11 review that we had -- the assessment -- or 12 the workshop that we had -- that we had 13 talked about. 14 Q. Do you know him in any other -- do 15 you know of his work in any or context other 01:49 PM 16 than his involvement in the FDA workshop? 17 A. I believe he's part of -- on the 18 plaintiffs' team. 19 Q. Sure. Do you know him to be a 20 skilled and capable scientist? 01:49 PM 21 A. From what I -- from what I know, 22 yes. 23 Q. And I'll represent to you that 24 Dr. Hecht testified that these estimates of 25 daily exposures that were provided by 01:49 PM</p>	<p style="text-align: right;">Page 534</p> <p>1 such a well-studied group of carcinogens, so 2 likely there are other papers that also study 3 the total nitrosamine exposure. 4 Q. So we talked earlier about Mylan's 5 API testing. 01:51 PM 6 Do you remember? 7 A. Yes. 8 Q. And remember we talked about the 9 fact that -- I asked you to assume a mean 10 concentration of .47 parts per million, which 01:51 PM 11 translate into a 150 nanogram maximum daily 12 dose associated with Mylan's product. 13 Do you remember all of that? 14 A. Yes. 15 Q. If Gushgari's sometimes are 01:51 PM 16 correct, the smoker consumes roughly 25,000 17 nanograms of valsartan a day, the 150 18 nanogram increase translates to a daily 19 exposure increase of about .6 percent, right? 20 A. Correct. 01:52 PM 21 Q. And for nonsmokers who consume 22 roughly 2,000 nanograms per day, the 150 23 nanogram intake represents about a 7.5 24 increase in daily nitrosamine intake, 25 correct? 01:52 PM</p>

<p style="text-align: right;">Page 535</p> <p>1 A. Right. Smoking -- exactly, has 2 high amounts of nitrosamines. 3 Q. And going back to Hidajat, you 4 would agree with me that there's absolutely 5 nothing in that occupational study that would 01:52 PM 6 suggest that a 1 to 7 percent short-term 7 increase in daily nitrosamine exposure will 8 cause cancer in humans? 9 MR. NIGH: Form objection. 10 A. As I said before, I focused on the 01:52 PM 11 quantification of NDMA by the quartiles and 12 that relationship to the increase in 10 13 different types of cancers. 14 BY MR. TRISCHLER: 15 Q. My question was different than 01:53 PM 16 that. 17 My question was, there is nothing 18 in the conclusions rendered by the Hidajat -- 19 the scientists in the Hidajat paper that 20 would suggests or support a conclusion that a 01:53 PM 21 1 to 7 percent short-term increase in daily 22 nitrosamine exposure will cause cancer in 23 humans, is there? 24 A. Yes, that seems reasonable, 25 correct. 01:53 PM</p>	<p style="text-align: right;">Page 537</p> <p>1 586 citations in your report, I assume we can 2 agree that not a single one of those 3 studies -- strike that. 4 Let me try again. 5 While you have 586 citations in 01:55 PM 6 your report, I assume we can agree that none 7 of the authors of any of those papers ever 8 reach a conclusion that a short-term increase 9 in daily NDMA intake on the order of 1 to 7 10 percent cause cancer in humans? 01:55 PM 11 MR. NIGH: Form objection. 12 A. So as I mentioned, I cited -- 13 correct, but as I mentioned, I cited -- I 14 focused on the epi studies that measured the 15 amount of NDMA in the diet, as well as the 01:55 PM 16 Hidajat study. And those ones clearly show 17 that an increased level of NDMA increases 18 your chance of getting cancer. And I didn't 19 cherry-pick. I included studies that were -- 20 it was a nonstatistical increase, as well as 01:56 PM 21 no increase. 22 So, as I said, so I did cite 23 papers with human epi -- with NDMA and only 24 one with NDEA. 25 BY MR. TRISCHLER: 01:56 PM</p>
<p style="text-align: right;">Page 536</p> <p>1 Q. And in the 500 -- I think it's 586 2 citations that you have in your report, are 3 you able to cite to me a single paper that -- 4 that would support a claim that a short-term 5 increase in daily nitrosamine intake on the 01:54 PM 6 order of 1 to 7 percent will cause cancer in 7 humans? 8 MR. NIGH: Form objection. 9 A. As I said before, I focused on 10 papers on NDMA and NDEA. It's very -- I 01:54 PM 11 didn't -- I didn't focus on total 12 nitrosamines. The question wasn't does total 13 nitrosamines caused cancer. It was does NDMA 14 or -- and NDEA cause cancer. 15 Q. All right. Let me rephrase my 01:54 PM 16 question then. 17 In the 586 citations in your 18 report, can you identify a single one that 19 would support a claim that a short-term 20 increase in daily NDEA intake on the order of 01:54 PM 21 1 to 7 percent cause cancer in humans? 22 A. Well, as we mentioned -- no. And 23 in NDEA, I only had one human epi study, the 24 Zhejiang with pancreatic cancer. 25 Q. And in the 5 -- and while you have 01:55 PM</p>	<p style="text-align: right;">Page 538</p> <p>1 Q. I think what I heard, I want to 2 make sure my record is clear, was the first 3 part of that answer was that you agree that 4 my statement was correct, true? 5 A. True. 01:56 PM 6 Q. Now, you -- I want to talk about 7 the Pottegard and Gom [sic] papers, if we 8 can. 9 You're familiar with those, 10 right. 01:57 PM 11 A. Yes. 12 MR. TRISCHLER: You can take -- 13 whoever is controlling the screen can 14 take down that paper, if you'd like. 15 Let me stop for a minute. 01:57 PM 16 MR. TRISCHLER: Dan, I have more 17 to go. I don't know where we are time 18 wise. I don't want to just plow ahead 19 in violation of the court's directive. 20 So can I check on time, because if we -- 01:57 PM 21 MR. NIGH: Do we know the total 22 time is? 23 The videographer says the total 24 time is 10 hours. 25 Do you agree? 01:57 PM</p>

<p style="text-align: right;">Page 539</p> <p>1 MR. TRISCHLER: I don't have any</p> <p>2 reason to dispute that. That's why I</p> <p>3 was asking.</p> <p>4 MR. NIGH: How much longer do you</p> <p>5 think you have, Clem? 01:57 PM</p> <p>6 MR. TRISCHLER: In all honesty,</p> <p>7 Dan, I probably have another hour at</p> <p>8 least. But I don't want to -- like I</p> <p>9 said, I don't want to --</p> <p>10 MR. NIGH: And how long does 01:58 PM</p> <p>11 the -- I don't recall who it was -- the</p> <p>12 firm from Duane Morris have?</p> <p>13 MR. BALL: At least an hour and a</p> <p>14 half.</p> <p>15 MR. NIGH: Okay. And how long 01:58 PM</p> <p>16 does Kara Kapke have?</p> <p>17 MS. KAPKE: It depends. I might</p> <p>18 not go at all.</p> <p>19 MR. NIGH: Do you have any</p> <p>20 questions now? 01:58 PM</p> <p>21 MR. TRISCHLER: I presume you're</p> <p>22 asking Kara that?</p> <p>23 MR. NIGH: Yes.</p> <p>24 MS. KAPKE: I anticipate that they</p> <p>25 will be covered by Clem or Rick, so at 01:58 PM</p>	<p style="text-align: right;">Page 541</p> <p>1 was clear, that defendants were to</p> <p>2 coordinate. We do not believe that</p> <p>3 happened. The coordinating that the</p> <p>4 judge directed, he did say I'll give you</p> <p>5 10 hours but you have to coordinate. 02:21 PM</p> <p>6 I also believe that the majority</p> <p>7 -- many of the documents and questions</p> <p>8 are not based on the length of his</p> <p>9 report, because they are actually based</p> <p>10 on the absence of what was in his report 02:21 PM</p> <p>11 and/or documents that he hadn't looked</p> <p>12 at, even though the basis for that</p> <p>13 amount of time was the length of the</p> <p>14 report.</p> <p>15 In addition, we recognize that, 02:21 PM</p> <p>16 you know, multiple other expert</p> <p>17 witnesses, they were all given 10 hours</p> <p>18 to question, even, you know, above and</p> <p>19 beyond plaintiffs' objections. Many of</p> <p>20 those other experts had reports that 02:21 PM</p> <p>21 were less than 30 pages, yet we still</p> <p>22 accommodated 10 hours of questioning of</p> <p>23 those experts.</p> <p>24 At this time we recognize that the</p> <p>25 people who stated that they have 02:22 PM</p>
<p style="text-align: right;">Page 540</p> <p>1 this point no.</p> <p>2 MR. NIGH: But if they're not, in</p> <p>3 other words, I think Clem's time, we're</p> <p>4 at 10 hours, and if you have questions</p> <p>5 now, I'm asking how long do you think 01:58 PM</p> <p>6 your questions would be?</p> <p>7 MS. KAPKE: Maybe 15 minutes.</p> <p>8 MR. NIGH: Okay. Let's go ahead</p> <p>9 and take a quick break. About 10</p> <p>10 minutes. 01:59 PM</p> <p>11 MR. TRISCHLER: Thanks.</p> <p>12 THE VIDEOGRAPHER: The time is</p> <p>13 1:58. We're off the record.</p> <p>14 (Recess taken at 1:58 p.m., to 2:20 p.m.)</p> <p>15 THE VIDEOGRAPHER: The time is 02:20 PM</p> <p>16 2:20. We're back on the record.</p> <p>17 MR. NIGH: It's currently 2:20</p> <p>18 here. We haven't taken a lunch break.</p> <p>19 In addition to that, I've consulted with</p> <p>20 my expert, and we simply would not have 02:20 PM</p> <p>21 the time to be able to accommodate all</p> <p>22 the witnesses here -- or all the counsel</p> <p>23 here that want at least another 2 hours</p> <p>24 and 45 minutes of questioning.</p> <p>25 We believe that the judge's order 02:21 PM</p>	<p style="text-align: right;">Page 542</p> <p>1 questions, Duane Morris -- additional</p> <p>2 questions, Duane Morris, and Clem</p> <p>3 Trischler are all lead counsel, as was</p> <p>4 the firm for the lead questioner, and we</p> <p>5 believe that, as lead counsel, they are 02:22 PM</p> <p>6 lead counsel for defendants not just</p> <p>7 their clients, far and above the duty to</p> <p>8 coordinate their time on behalf of the</p> <p>9 MDL and the direction given by Judge</p> <p>10 Vanaskie. 02:22 PM</p> <p>11 On the flip side, we recognize</p> <p>12 that Kara Kapke has stated that she has</p> <p>13 15 minutes of questioning. And so if</p> <p>14 the defendants are prepared, we are okay</p> <p>15 going another 15 minutes, and then we're 02:22 PM</p> <p>16 going to have to conclude at that point.</p> <p>17 So if Kara Kapke is ready to do</p> <p>18 her questioning, we will offer the</p> <p>19 witness to sit for another 15 minutes</p> <p>20 for her questioning. 02:23 PM</p> <p>21 MR. FOWLER: I will respond first,</p> <p>22 Counsel. I think the record will speak</p> <p>23 for itself as to how the time was used</p> <p>24 and the documents that were shown the</p> <p>25 witness. I disagree with your 02:23 PM</p>

<p style="text-align: right;">Page 543</p> <p>1 characterization that the questions were 2 about what was not in his report. All 3 of the questions were focused on his 4 opinions, and he was shown documents -- 5 whether or not he considered them, he 02:23 PM 6 was shown some documents not referenced 7 in his report. 8 But with 586 citations and a 9 200-page report; and, most importantly, 10 a witness who would run on page after 02:23 PM 11 page after page of nonresponsive answers 12 to what was -- were very straightforward 13 questions, I think this transcript will 14 speak for itself, and I think -- you 15 know, if you're going to force 02:24 PM 16 defendants to get a ruling to get a 17 couple hours time, I think that's going 18 to be a short walk. 19 Because this transcript is like 20 nothing I've seen. And I looked and it 02:24 PM 21 will speak for itself, Counsel, and if 22 you -- and I appreciate your position, 23 and defendants obviously have means and 24 options to address that with the court, 25 which we may well do. 02:24 PM</p>	<p style="text-align: right;">Page 545</p> <p>1 to do with the defendants in the manner 2 in which issues were allocated, but more 3 to do with how questions were answered 4 or not answered. But, again, the record 5 on that well speak for itself. 02:25 PM 6 Judge Vanaskie himself recognized 7 that we have a unique litigation here 8 where there are over 50 defendants. 9 While we have common interest, we also 10 have individual interest and unique 02:26 PM 11 facts among us. The fact that we have 12 two or three examiners every expert 13 deposition taking the depositions of the 14 experts in a way that's not cumulative 15 is entirely appropriate, consistent with 02:26 PM 16 what the court ruled. 17 And the fact of the matter, we 18 have one additional expert deposition 19 for the plaintiff to complete. We need 20 a few more hours to do it. I understand 02:26 PM 21 your position, while I can respect it, I 22 disagree with it, but I understand it. 23 And I think we'll have to assess 24 the situation amongst ourselves on the 25 defense side, take a look at the 02:26 PM</p>
<p style="text-align: right;">Page 544</p> <p>1 But I disagree with your 2 characterization. I think this record 3 speaks for itself of at least two hours 4 that were unnecessary based upon run-on, 5 nonresponsive answers. 02:24 PM 6 MR. NIGH: Does anybody else on 7 defense want to speak? 8 MR. TRISCHLER: Yes, thank you. 9 This is Clem Trischler. Obviously, for 10 madam court reporter so she knows who's 02:24 PM 11 speaking. 12 I am very cognizant of the time 13 limitation established by Judge 14 Vanaskie. I think everyone on the 15 defendant's side is very cognizant of 02:25 PM 16 that time limitation that we all worked 17 very diligently through the expert phase 18 of this case to comply with those time 19 limits. 20 Every deposition up until this 02:25 PM 21 point, we've been able to complete the 22 deposition within the time period 23 allowed by the court. And I concur with 24 Mr. Fowler that the reasons that this 25 deposition is not finished have little 02:25 PM</p>	<p style="text-align: right;">Page 546</p> <p>1 transcript that bears out what I think 2 it does, then I think we'll be raising 3 the issue with Judge Vanaskie and asking 4 that the witness be brought back so that 5 I have an opportunity to finish my exam. 02:27 PM 6 I've not been repetitive with the 7 witness. I've not covered issues that 8 were previously covered, but these are 9 important issues that go to the heart of 10 the causation issues in this case, and I 02:27 PM 11 think that asking the witness to come 12 back for a few more hours so that those 13 issues can be fairly covered is not an 14 unreasonable burden under the 15 circumstances. 02:27 PM 16 So I'll turn it over to anyone 17 else that wants to add anything, but I 18 think -- I think we obviously have to 19 agree to disagree. Our position is that 20 the deposition is not concluded. My 02:27 PM 21 questioning is not finished, and I'll 22 reserve the right to continue when so 23 directed by the court. 24 THE BALL: This is Mr. Ball. I 25 concur with what my two colleagues have 02:28 PM</p>

<p style="text-align: right;">Page 547</p> <p>1 said, my two co-counsel said.</p> <p>2 And, Mr. Nigh, I want to assure</p> <p>3 you that none of the questions I have</p> <p>4 will in any way be cumulative.</p> <p>5 MR. NIGH: Anybody for defense 02:28 PM</p> <p>6 want to speak? Ms. Kapke?</p> <p>7 MS. KAPKE: I can ask a few of my</p> <p>8 questions, but I echo what the other</p> <p>9 counsel have said. I also -- I have</p> <p>10 coordinated with those counsel, and my 02:28 PM</p> <p>11 preference is to feed any questions that</p> <p>12 I have to them, but they have not had</p> <p>13 the opportunity to finish their</p> <p>14 questioning, so I don't think it's</p> <p>15 appropriate for me to ask the questions 02:29 PM</p> <p>16 that I would ask if they do not ask</p> <p>17 them. Because they haven't had their</p> <p>18 complete opportunities and chance to ask</p> <p>19 those questions.</p> <p>20 So I think the best thing for me 02:29 PM</p> <p>21 to do is to, again, say that the other</p> <p>22 defendants would like to go first, and</p> <p>23 I'd like them to finish their questions</p> <p>24 before I ask my questions.</p> <p>25 MR. NIGH: Well, my -- I'm sorry, 02:29 PM</p>	<p style="text-align: right;">Page 549</p> <p>1 I disagree that the record will</p> <p>2 speak for itself. I actually believe</p> <p>3 that, you know, defense counsel has a</p> <p>4 choice as to how they want to ask</p> <p>5 questions and what questions they want 02:30 PM</p> <p>6 to ask. But I do believe the record</p> <p>7 will show numerous cumulative questions,</p> <p>8 and had those questions been eliminated,</p> <p>9 there would have been enough time to</p> <p>10 cover the other questioners and the 02:31 PM</p> <p>11 information that they wanted to cover.</p> <p>12 In addition, I believe that the</p> <p>13 loaded questions that were chose to be</p> <p>14 asked on numerous occasions lead to</p> <p>15 lengthier answers. That's a choice by 02:31 PM</p> <p>16 the defense counsel and that's the</p> <p>17 choice they made.</p> <p>18 As we can see from other</p> <p>19 questioners, they have far less</p> <p>20 lengthy -- or other questioner, they had 02:31 PM</p> <p>21 far less lengthier answers because they</p> <p>22 weren't loaded questions. Okay. That's</p> <p>23 all I have.</p> <p>24 THE VIDEOGRAPHER: The time is</p> <p>25 2:31. We are off the record. 02:31 PM</p>
<p style="text-align: right;">Page 548</p> <p>1 just to clarify your position. Our</p> <p>2 offer is for you to be able to go now,</p> <p>3 as the only defense counsel here who</p> <p>4 doesn't sit as lead counsel who has</p> <p>5 stated that they have questions of this 02:29 PM</p> <p>6 witness and thought that, as of right</p> <p>7 now, you would have about 15 minutes of</p> <p>8 questions.</p> <p>9 Is it your statement that you're</p> <p>10 rejecting that offer? 02:29 PM</p> <p>11 MS. KAPKE: Yes. I'm rejecting</p> <p>12 that offer because I think the other</p> <p>13 defendants need to finish their</p> <p>14 questioning first.</p> <p>15 MR. NIGH: Okay. Anybody else on 02:30 PM</p> <p>16 the defense have a position?</p> <p>17 Hearing none, I will also respond</p> <p>18 that I think any attempt to raise</p> <p>19 enlargement of time motions are</p> <p>20 untimely, given the calendar that we 02:30 PM</p> <p>21 have set out. And given the time on my</p> <p>22 expert's witness -- on the expert</p> <p>23 witness's calendar, and I think that</p> <p>24 that's just one more thing we have to</p> <p>25 consider. 02:30 PM</p>	<p style="text-align: right;">Page 550</p> <p>1 (Deposition suspended 2:32 p.m.)</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p>1 COMMONWEALTH OF MASSACHUSETTS</p> <p>2 SUFFOLK, SS.</p> <p>3</p> <p>4 I, Sandra A. Deschaine, Registered</p> <p>5 Professional Reporter and Notary Public</p> <p>6 within and for the Commonwealth of</p> <p>7 Massachusetts at large, do hereby certify</p> <p>8 that the videotaped deposition of Dipak</p> <p>9 Panigrahy, M.D., Day 2, in the matter of In</p> <p>10 Re: Valsartan, Losartan and Irbesartan</p> <p>11 Products Liability Litigation, at the offices</p> <p>12 of Greenberg Traurig, One International</p> <p>13 Place, Boston, Massachusetts, on September 9,</p> <p>14 2021, taken and transcribed by me; that the</p> <p>15 witness provided satisfactory evidence of</p> <p>16 identification as prescribed by Executive</p> <p>17 Order 455 (03-13) issued by the Governor of</p> <p>18 the Commonwealth of Massachusetts; that the</p> <p>19 transcript produced by me is a true record of</p> <p>20 the proceedings to the best of my ability;</p> <p>21 that the witness is reading and signing; that</p> <p>22 I am neither counsel for, related to, nor</p> <p>23 employed by any of the parties to the action</p> <p>24 in which this deposition was taken, and</p> <p>25 further that I am not a relative or employee</p> <p>of any attorney or counsel employed by the</p> <p>parties thereto, nor financially or otherwise</p> <p>interested in the outcome of the action, on</p> <p>this 17th day of September 2021.</p> <p><i>Sandra A. Deschaine</i></p> <p>Sandra A. Deschaine</p> <p>Registered Professional Reporter</p> <p>My Commission Expires:</p> <p>July 5, 2024</p>	<p>1 ERRATA SHEET</p> <p>2 DAY 2</p> <p>3 IN RE: VALSARTAN, LOSARTAN AND IRBESARTAN</p> <p>4 DIPAK PANIGRAHY, M.D. - SEPTEMBER 9, 2021</p> <p>5</p> <p>6 Page Line Change/Correction</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p> <p>25 _____</p>
<p>Page 552</p> <p>1 SIGNATURE PAGE</p> <p>2 DAY 2</p> <p>3 IN RE: VALSARTAN, LOSARTAN AND IRBESARTAN</p> <p>4 DIPAK PANIGRAHY, M.D. - SEPTEMBER 10, 2021</p> <p>5</p> <p>6 I, the undersigned, declare under penalty</p> <p>7 of perjury that I have read the foregoing</p> <p>8 transcript, and I have made any corrections,</p> <p>9 additions or deletions that I was desirous of</p> <p>10 making; that the foregoing is a true and</p> <p>11 correct transcript of my testimony contained</p> <p>12 therein.</p> <p>13</p> <p>14 Executed this _____ day of</p> <p>15 _____,</p> <p>16</p> <p>17 at _____,</p> <p>18 (CITY) (STATE)</p> <p>19</p> <p>20 -----</p> <p>21 DIPAK PANIGRAHY, M.D.</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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